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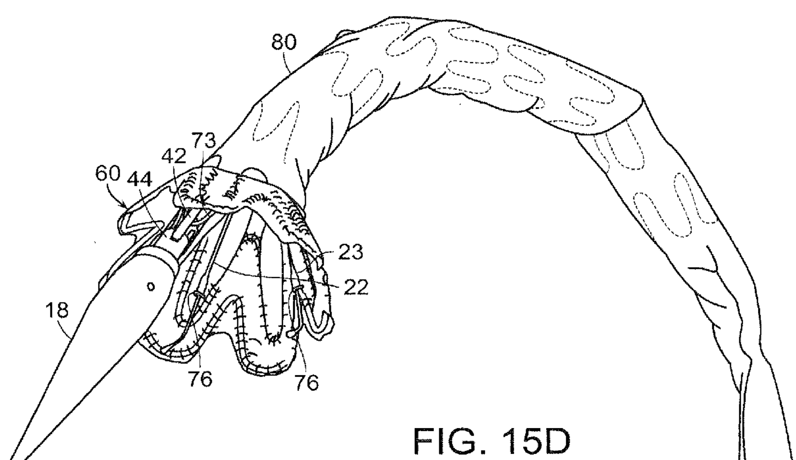

FIG. 15D

(57) Abstract: A system for implanting a prosthesis includes a control lumen and a nose cone affixed at a distal end of the control lumen. At least one supporting wire is affixed at one end, is substantially parallel to a major axis of the control lumen and is free at an opposite end, wherein the free end of at least one of the supporting wires is arcuate. Alternatively, a system for implanting a prosthesis includes at least one suture extending from a nose cone affixed to a distal end of a control lumen, The suture extends from the nose cone to a proximal end to a stent graft extending about the control lumen and from the stent graft to a fixed location on the control lumen. The suture is releasable from the stent graft by remote activation, whereby the suture separates from the nose cone to thereby deploy the stent graft.

WO 2010/105195 A2

B35

SYSTEM AND METHOD FOR DEPLOYING AN ENDOLUMINAL PROSTHESIS AT A SURGICAL SITE

RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Application No. 61/160,052, filed on March 13, 2009 and of U.S. Provisional Application No. 61/255,339, filed on October 27, 2009. The teachings of these provisional applications are incorporated herein by reference in their entirety.

BACKGROUND OF THE INVENTION

Endoluminal prostheses for treatment of arterial disease have come into wide use over the past several years. Typically, such prosthesis include a luminal graft material of woven polyethylene terephthalate (PET) supported by self-expanding stents, which are often formed of a shape memory alloy.

Endoluminal stent grafts, so called because they are deployed within a lumen of a blood vessel, are employed to support diseased arterial tissue, such as arterial tissue that has been weakened to thereby form aneurysms, psuedoaneurysms, dissections, penetrating ulcers, and intramural hematomas. Arteries that are most susceptible to these type of disease states, and which would be treatable by implantation of endoluminal stent grafts include, for example, the abdominal aorta, the thoracoabdominal aorta, the descending thoracic aorta, the aortic arch, and the ascending aorta.

Generally, endoluminal prostheses are implanted by femoral access through the femoral artery of a patient. Alternatively, endoluminal devices can be implanted by transapical access through the apex of the heart and the left ventricle to, for example, the ascending aorta and may, when deployed, essentially abut the aortic valve at the sinotubular junction, the region of the ascending aorta between the aortic sinuses (of Valsalva) and where the normal configuration of the aorta is attained.

Implantation of a self-expanding stent graft prosthesis generally requires that it be constrained within a narrow diameter during delivery to the deployment site

within the patient. Often, the diameter is constrained by containing the prosthesis within at least one sheath that is capped at a distal end, respective to the surgeon, with a pliable nose cone. The sheath and nose cone are guided through the lumen of the artery by a guidewire that extends axially through and extends from the nose cone of the delivery device within which the prosthesis is contained. Once the nose cone and sheath have been advanced to the surgical site where the prosthesis is to be deployed, the sheath containing the prosthesis can be rotated, if necessary, to properly orient the prosthesis, and then one or more sheaths are retracted to allow the prosthesis to expand, thereby deploying the prosthesis at the intended treatment site.

Several problems can occur by remote deployment of endoluminal prosthesis from a constraining sheath. For example, if the portion of the aorta where the prosthesis is to be deployed has an extreme tortuosity or tight radius of curvature, such as the arch of the aorta, which is arcuate, or because the disease state of the aorta has caused the aorta to have an irregular shape, simple retraction of the sheath, or sheaths, from the prosthesis can cause the proximal end (cranially, with respect to the patient) of the stent graft to fail to properly align with the arterial wall. For example, a portion of the proximal end of the stent graft can rotate backward, toward the surgeon, adjacent to the curve in the vessel thereby causing a failure of the proximal end of the stent graft to form a seal with the artery. This phenomenon is commonly referred to as a "retroflex." Most commonly, rotation of a portion of the proximal end of the stent graft during deployment occurs at an inferior side of a stent graft being deployed within the aortic arch, which has a relatively large diameter. Another problem includes the formation of a "bird's beak," also referred to as a "gap," caused by the stent graft failing to properly conform to an inferior portion curve of the aorta, which most commonly occurs as a result of a deployment sequence that forces the most proximal covered stent of the prosthesis to be deployed last.

Another problem occurs when the stent graft must be deployed close to the junction between the ascending aorta and the aortic valve. Specifically, the nose cone employed to assist guidance of the endoluminal prosthesis to the surgical site

restricts the ability of the surgeon to deploy the prosthesis contained in the sheath as close to the ascending aorta at its point of origin.

Therefore, a need exists for a delivery system for implanting a prosthesis and methods of implanting a prosthesis that minimizes or overcomes the above-referenced problems.

SUMMARY OF THE INVENTION

The invention generally is directed to a system and method for implanting a prosthesis and, specifically, for implanting an endoluminal prosthesis at a diseased site of an aorta.

In one embodiment of the invention, the system includes a control lumen, a nose cone fixed at a distal end of the control lumen, and at least one supporting wire fixed at one end, substantially parallel to a major axis of the control lumen and free at an opposite end. The free end of at least one of the supporting wires is arcuate.

In another embodiment, the system of the invention includes a control lumen, a nose cone fixed at a distal end of the control lumen, a stent graft extending about the control lumen, and at least one suture extending from the nose cone to a proximal end of the stent graft and from the stent graft to a fixed location on the control lumen. The suture is releasable from the stent graft by remote activation, whereby retraction of the control lumen releases the suture from the nose cone to thereby deploy the stent graft.

In still another embodiment of the invention, the system includes a control lumen, a nose cone fixed at a distal end of the control lumen, and an inner sheath extending above the control lumen that defines a distal opening at a distal end of the inner sheath. The nose cone is retractable within the inner sheath.

In yet another embodiment of the invention, the invention is a method for implanting a prosthesis that includes delivering a stent graft through an artery to an aneurysm site of a patient, the stent graft being radially constrained by an inner sheath and supported at least in part by a control lumen. The stent graft is also longitudinally constrained by at least one supporting wire extending from a nose cone, from the control lumen or from an outer control tube extending about and

slideable along the control lumen, wherein the free end of at least one of the supporting wires is arcuate and extends through a loop hole within a proximal end of the stent graft. The inner sheath is partially retracted from the stent graft, whereby the supporting wire at least partially restricts longitudinal movement of the proximal end of the stent graft until the proximal end of the stent graft is secure within the artery, to thereby prevent rotation of a portion of the proximal end of the stent graft at an inferior portion of the artery. The inner sheath and supporting wire are then retracted, thereby removing the supporting wire from the loop and deploying the stent graft within the artery at the aneurysm site of the patient. The inner sheath and supporting wire can be jointly retracted, thereby removing the supporting wire from the loop and deploying the stent graft within the artery at the aneurysm site of the patient.

In one embodiment, the method further includes the steps of retracting the nose cone within the stent graft after partially retracting the inner sheath. The stent graft is then advanced to a final position within the artery. Thereafter, the inner sheath, nose cone and supporting wires are retracted to fully deploy the stent graft within the artery at the aneurysm site of the patient.

In another embodiment of the invention, the method includes delivering a stent graft through an artery to an aneurysm site of the patient. The stent graft is radially constrained by an inner sheath and supported at least in part by a control lumen, and is further constrained by at least one suture extending from a nose cone at a distal end of the control lumen to a proximal end of the stent graft and extending from the proximal end of the stent graft to a fixed location on the control lumen. This suture is releasable from the nose cone and the stent graft by remote activation. The inner sheath is retracted from the stent graft, whereby the suture at least partially restricts longitudinal movement of the proximal end of the stent graft until the proximal end of the stent graft is secure within an artery, thereby preventing rotation of a portion of the proximal end of the stent graft at an inferior portion of the artery. This suture is then remotely activated, whereby the suture is released from the nose cone and releases the stent graft. The inner sheath is then retracted to thereby deploy the stent graft within the artery at the aneurysm site of the patient.

In still another embodiment, the invention is a method for implanting a prosthesis comprising a control lumen, a nose cone fixed at a distal end of the control lumen, a sheath lumen extending about the control lumen and slideable along the control lumen and an inner sheath extending distally from the sheath lumen and about the control lumen between the nose cone and the sheath lumen, the inner sheath defining at least one through-hole at a proximal end of the inner sheath proximate to the sheath lumen.

In yet another embodiment, the invention is a system for implanting a prosthesis comprising a control lumen, a nose cone fixed at a distal end of the control lumen, an outer control tube extending about the control lumen, an apex clasp at a distal end of the outer control lumen and slideable along the control lumen, a sheath lumen extending about the control lumen, an inner sheath extending distally from the sheath lumen about the outer control tube, the inner sheath including a triangular piece at a distal end of the inner sheath; and a stent graft between the outer control tube and the inner sheath, the stent graft including a proximal end proximate to the nose cone having a clasping stent at the proximal end, wherein the clasping stent has at least one exposed proximal apex releasably held by the apex clasp.

In a further embodiment, the invention is a method for implanting a prosthesis, comprising the steps of delivering a stent graft through an artery to a point distal, relative to the patient, of an aneurysm site of a patient, the stent graft being radially constrained by an inner sheath, and affixed to an outer control tube, and wherein the inner sheath is constrained by an introducer sheath, the stent graft and the inner sheath each including at least one radiopaque marker on superior portions of the stent graft and the inner sheath, the radiopaque markers being separated along a major longitudinal axis of the inner sheath; advancing the inner sheath, the stent graft and the outer control lumen beyond the introducer sheath until the stent graft spans the aneurysm site of the patient; partially retracting the inner sheath from the stent graft, whereby the radiopaque marker of the stent graft overlaps to the radiopaque marker of the inner sheath; positioning a proximal end of the stent graft within the artery; and fully retracting the inner sheath to thereby fully deploy the stent graft within the artery.

This invention has many advantages. For example, the supporting wire of the system for implanting a prosthesis provides longitudinal support for at least a portion of the proximal end of a stent graft, such as a portion of the proximal end of the stent graft that is located an inferior, or inner, portion of a curve, of the aortic arch. This longitudinal restraint limits rotation of a portion of a proximal end of an endoluminal stent at an inferior portion of the aortic arch lumen, thereby causing the proximal end of the stent graft to be properly seated in a plane that is essentially transverse to a major longitudinal axis extending through the aortic lumen at the proximal end of the stent graft. Proper seating of the proximal end of the stent graft prevents seepage of blood beyond and under the prosthesis, thereby increasing the likelihood of successful implant and prolonging useful life of the prosthetic implant. Further, retraction of a nose cone within the stent graft prior to its deployment enables the prosthesis to be deployed within an ascending aorta of a patient essentially within abutting relation with a valve of the heart, thereby providing greater flexibility to the surgeon when placing the stent graft within a patient. In addition, retraction of the nose cone within the stent graft prior to deployment within an abdominal aorta of a patient permits refinements in the placement of the stent graft relative to the aneurysm site in the abdominal aorta, thereby providing greater flexibility to the surgeon when placing the stent graft within the patient. Another advantage of the invention is an inner sheath defining at least one through-hole that permits perfusion or continued flow of blood during deployment of a stent graft.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

FIG. 1 depicts a prior art system for implanting a stent graft in a lumen of an aorta.

FIG. 2 depicts prior art deployment of a stent graft in a lumen of a curved portion of an aorta from a sheath that permits a proximal end of the stent graft to rotate backward at an inferior portion.

FIG. 3 depicts prior art full deployment of a stent graft with a kink caused by retroflex rotation of the proximal end of the stent graft.

FIG. 4 depicts prior art deployment of a stent graft with a "bird's beak" caused by a sequence of deployment that frees the first proximal covered stent last.

FIG. 5A depicts an embodiment of a system of the invention for implanting a prosthesis.

FIGS. 5B and 5C depict embodiments of systems of the invention that include an apex clasp for implanting a prosthesis.

FIG. 6 depicts another embodiment of a system of the invention for implanting a prosthesis.

FIGS. 7A, 7B and 7J depict side and longitudinal cross-section views of a portion of embodiments of a system of the invention for implanting a prosthesis.

FIGS. 7C and 7K depict embodiments of a stent graft for use in a system of the invention for implanting a prosthesis.

FIG. 7D depicts a crown stent and a clasping stent, with exposed proximal apices, located on the inside of a lumen defined by the graft suitable for use by the invention.

FIG. 7E depicts engagement of the exposed proximal apices of the clasping stent with the tines of an apex clasp of the invention.

FIG. 7F depicts an embodiment of the stent graft in an arch configuration, as it would be at a surgical site.

FIGS. 7G, 7H and 7I depict various embodiments of the bifurcated stent grafts suitable for use with the system of the invention for implanting a prostheses.

FIG. 8 depicts suture loops on an inside surface of the stent graft.

FIGS. 9A and 9B depict embodiments of an inner sheath in a system of the invention for implanting a prosthesis.

FIG. 10 depicts an alternative embodiment of a distal end of an inner sheath in a system of the invention for implanting a prosthesis.

FIGS. 11A and 11B depict other alternative embodiments of an inner sheath in a system of the invention for implanting a prosthesis.

FIG. 12A depicts an embodiment of the invention wherein a nose cone defines a proximal cavity at the proximal end of the nose cone.

FIG. 12B depicts an embodiment of the invention wherein an inner sheath includes at least one radiopaque marker affixed to a superior portion of the inner sheath.

FIG. 12C depicts a fluoroscopic rendering of an embodiment of the methods of the invention whereby partial deployment of a stent graft at a surgical site is indicated by alignment of at least one radiopaque marker of the stent graft and at least one radiopaque marker of an inner sheath.

FIG. 13 depicts an embodiment of a system of the invention for implanting a prosthesis where an inner sheath containing a stent graft is constrained prior to delivery by a introducer sheath.

FIGS. 14A-14E depict an embodiment of the invention during implantation of a prosthesis at an aneurysm site.

FIGS. 15A-15E depict different views of an embodiment of the invention during deployment of a prosthesis.

FIGS. 15B, 15C and 15E depict fluoroscopic renderings of embodiments of the invention.

FIG. 16 depicts an embodiment of the inner sheath in the system of the invention.

FIGS. 17 and 18 depict yet another embodiment of the invention for implanting a prosthesis.

FIGS. 19A-19D depict still another embodiment of the invention for implanting a prosthesis.

FIGS. 20A and 20B depict embodiments of the invention, for implanting a prosthesis by entry through the left ventricle of a patient's heart.

FIG. 21A depicts an alternative embodiment of the invention, that includes at least one suture and an apex clasp.

FIG. 21B depicts another alternative embodiment of the invention, that includes at least one suture.

FIGS. 22A and 22B depict an embodiment of the invention that includes an inner sheath having at least one through-hole.

DETAILED DESCRIPTION OF THE INVENTION

The features and other details of the invention, either as steps of the invention or as combinations of parts of the invention, will now be more particularly described and pointed out in the claims. It will be understood that the particular embodiments of the invention are shown by way of illustration and not as limitations of the invention. The principal features of this invention can be employed in various embodiments without departing from the scope of the invention.

The present invention generally is directed to a system and method for implanting an endoluminal prosthesis within a vessel (e.g., artery) of a patient. The system and method employ at least one supporting wire to provide longitudinal support to prevent rotation toward the surgeon of a portion of a proximal end of an endoluminal stent graft during deployment of the stent graft. The proximal end of the stent graft is thereby properly seated at the surgical site proximate to an aneurysm or other diseased portion of an aorta, before complete deployment of the stent graft.

The invention also includes a system that provides for retraction of a nose cone of a delivery system within an endoluminal stent graft prior to complete deployment of the stent graft, thereby permitting abutment of the stent graft to another anatomical feature, such as a heart or arterial valve, during deployment. In still another embodiment, an endoluminal graft delivery system includes a sheath at one end of the endoluminal graft, the graft being releasable from the endoluminal graft and permitting perfusion distal to the graft.

As represented in FIGS. 1-4, deployment of stent graft 1, also referred to herein as an “endoluminal prosthesis” or “prothesis,” within the lumen of an aorta 2, particularly a portion of an aorta that exhibits a curvature, such as the arch of the aorta, from the end of a sheath 3, can cause at a proximal end 4 of the prosthesis to rotate backward at an inferior portion 5 of, in a generally longitudinal direction, toward the surgeon, as shown in FIG. 2, thereby causing the fully deployed

prosthesis to be folded at the proximal end and creating a kink 6 within the prosthesis, as shown in FIG. 4 or distal buckling of the entire proximal end of the stent graft. FIG. 4 depicts the formation of "bird's beak" 7. The formation of a "bird's beak" can occur with a prosthesis having a bare stent or stent covered with graft material at the proximal end of the prosthesis.

In an embodiment, the invention employs at least one supporting wire as a component of a system for delivering a prosthesis to provide longitudinal support, whereby rotation of the proximal end 4 of the prosthesis during retraction of a constraining sheath is prevented, thereby resulting in deployment of the prosthesis in a fully extended manner, whereby folding back of an inferior portion of a proximal end of the prosthesis and consequent buckling, or crimping, of the prosthesis, as shown in FIGS. 3 and 4, is essentially prevented. Retroflex or such rotation and consequent buckling of the prosthesis can occur in grafts with or without bare stents. A "bird's beak" is particularly prevalent in prostheses that do not have bare stents extending from the proximal (cranial) end of the graft portion of a stent graft. Such stent graft, also known as "non-bare stent grafts," can be employed as prostheses that, when deployed, abut other anatomical structures, such as heart valves. Lack of bare stents at the proximal end of an endoluminal stent graft can make deployment of the stent graft more difficult by providing limited opportunities to control expansion of self-expanding stents of the stent graft as a constraining sheath is retracted during deployment. As a consequence, the inferior portion or the entire portion of a proximal end of an endoluminal stent graft, has a tendency, as described above, to rotate back in a generally longitudinal direction to thereby cause an imperfect seal, possible retroflex or formation of a "bird's beak," as discussed above with respect to FIGS. 3 and 4. The systems and methods of the invention prevent retroflex and the formation of a "bird's beak."

In embodiments of the invention, represented in FIGS. 5A, 5B, 5C, systems 10, 11 and 13, respectively, include, control lumen 12. Control lumen 12 typically is formed of a suitable metal, such as stainless steel, a shape memory metal or a super elastic nickel-titanium alloy, such as a nitinol shape memory alloy; a polymer, such as polyether ether ketone (PEEK); or any combination of a metal, alloy or polymer, in particular, a combination of a metal and an alloy. Control lumen 12

typically is arcuate and defines a lumen extending therethrough having a diameter in a range of between, for example, in a range of about 0.0040 inches (about 0.0030 inches to about 0.0050 inches) ID (inner diameter) and about 0.050 inches (about 0.040 inches to about 0.060 inches) OD (outer diameter). Control lumen 12 includes proximal end 14 and distal end 16.

Nose cone 18 is fixed at distal end 16 of control lumen 12. Nose cone 18 is formed of a suitable material, such as TECOTHANE®, thermoplastic polyurethane elastomer polyether. Control lumen 12 extends through nose cone 18, thereby permitting guidewire 20 to extend through control lumen 12 and from nose cone 18, whereby systems 10, 11, 13 can be advanced along guidewire 20 endoluminally and through an artery (e.g., aorta) of a patient to a surgical site (e.g., ascending aorta, thoracic aorta, descending aorta, abdominal aorta).

Supporting wires 22, 23 are fixed at one end and extend substantially parallel to a major axis of control lumen 12. Supporting wires 22, 23 are free at an end opposite to the fixed end. As shown in FIGS. 5A, 5B and 5C, supporting wires 22, 23 are fixed at proximal ends 24, 25 and are free at distal ends 26, 27. In an embodiment, distal ends 26, 27 of supporting wires 22, 23 are arcuate. Further, supporting wires 22, 23 include cantilever sections 28, 29 that are proximate (near) to proximal ends 24, 25. Typically, supporting wires 22, 23 are formed of a suitable surgical-grade metal, such as stainless steel, or a super-elastic alloy, preferably a nitinol shape memory alloy. The length of supporting wires 22, 23 typically is in a range of about 50 mm to about 75 mm or in a range of about 75 mm to about 100 mm, preferably about 75 mm. The wire diameter at the arcuate end is reduced to ensure that it is easy to straighten and remains very flexible and atraumatic. Supporting wires prevent retroflex during deployment of a stent graft, as depicted in FIG. 4.

Outer control tube 30, shown in FIGS. 5B and 5C, extends about control lumen 12 and is slideable along control lumen 12. Examples of suitable materials of control lumen 12 include PEEK. Typically, outer control tube 30 has an internal diameter in a range of between about 0.050 inches and about 0.060 inches, preferably about 0.055 inches, and an outer diameter in a range of between about 0.070 inches and about 0.075 inches, preferably about 0.071 inches, whereby the

thickness of a wall of outer control tube 30, typically, has a range of between about 0.007 inches and about 0.009 inches, preferably about 0.008 inches.

Outer control tube 30 includes proximal end 32 and distal end 34. Buttress 36 is affixed to outer control tube 30, such as at proximal end 32 of outer control tube 30. Supporting wires 22 are fixed at inferior side of buttress 36, thereby causing supporting wires 22 to be clustered. Buttress 36 is formed of a suitable material, such as PEEK, and typically has an outer diameter in a range of between about 0.200 inches and about 0.300 inches, such as about 0.200 inches, about 0.225 inches, about 0.250 inches, about 0.275 inches and about 0.300 inches. Buttress 36 can be sized to fit into the inner diameter of introducer sheath 92. In another embodiment, not shown, at least one supporting wire 22, 23 is fixed directly to control lumen 12, without fixing element 37, and fixing element 37 need not be present.

Pusher support tube 38 extends proximally from buttress 36. In another embodiment, shown in FIG. 5C, wires 22, 23 are fixed to control lumen 12 by fixing element 37 which is separated from buttress 36 and pusher support tube by a length of outer control tube 30. Examples of suitable materials of fixing element 37 include PEEK. Fixing element 37 can be an oblong shape to reduce profile on the opposite side of where the supporting wires are attached.

Apex clasp 40, shown in FIGS. 5B and 5C, is fixed to distal end 34 of outer control tube 30 and is slidable along control lumen 12 with movement of outer control tube 30. Apex clasp 40 includes tines 42 that are in mating relation with receiving section 44 of the apex clasp 40. Typically, tines 42 of apex clasp 40 are formed of a suitable material, such as stainless steel, while receiving section 44 is formed of a suitable material, such as PEEK or stainless steel. Tines 42 are dimensional to receive at least one proximal apex of a clasping stent of a stent graft (FIG. 7E), whereby actuation of apex clasp 40, by retraction of tines 42 from receiving section 44 or nose cone 18 will release the exposed proximal apex of at least one clasping stent during deployment of the stent graft at a surgical site.

Optionally, apex clasp 40 is operable separately from outer control tube 30, whereby outer control tube 30 and supporting wires 22, 23 can be retracted independently of actuation of apex clasp 40, as also shown in FIG. 5C. Separate and

independent actuation of apex clasp 40 can be obtained by attachment of apex clasp 40 to tube 43 that extends between outer control tube 30 and control lumen 12.

In an alternative embodiment, represented in FIG. 6, apex clasp 40 is attached to outer control tube 30, fixing element 37 is attached to outer control tube 30 and supporting wires 22, 23 are attached to fixing element 37, whereby apex clasp 40 and supporting wires 22, 23 are jointly retracted by actuation or movement of outer control tube 30. Further, in an alternative embodiment, supporting wires 22, 23 include bulbous tips 50, 51 at distal ends 26, 27, respectively, and stops 52, 53, respectively, having a diameter greater than that of supporting wires 22, 23, proximate to free and distal ends 26, 27 of supporting wires 22, 23. Stent graft 60, shown in FIGS. 7A, 7B and 7J, extends about control lumen 12, supporting wires 22, 23 and outer control tube 30 of system 10. Inner sheath 80 extends about stent graft 60, which, in turn, extends about pusher support tube 38 and is independent and moveable from pusher support tube 38. Sheath lumen 81 typically is formed of PEBAX®, polyether block amine and can include a stainless steel braiding on the interior. Inner sheath 80 extends about stent graft 60, thereby at least partially constraining stent graft 60 prior to deployment at a surgical site. Radiopaque marker 78 is affixed to superior side of stent graft 60 at a distance in a range of about 40 mm and about 60 mm, such as about 40 mm, about 45 mm, about 50 mm, about 55 mm, about 60 mm distal, to proximal end 70 of stent graft 60. Radiopaque marker 88 is fixed to inner sheath 80 by, for example, at least one stitch, and is longitudinally aligned with, but offset from radiopaque marker 78 of stent graft 60. Radiopaque marker 88 can be asymmetric in shape, such as a D-shape, as shown in FIGS. 12B, 12C and 15C.

As shown in FIGS. 7C and 7K stent graft 60 includes graft 62 and at least one radiopaque marker 79. In an embodiment, radiopaque marker 79 is a dumb-bell or elongate shape. Examples of suitable materials of graft 62 include PET. Typically, the PET of graft 62 is woven. Alternatively, stent graft 60 can be a bifurcated stent graft having two long legs, and a short and long leg, or two short legs, as shown in FIGS. 7G, 7H, 7I, respectively. Graft 62 is supported by stents 64, which typically are formed of a suitable material, such as a shape memory metal or super elastic nickel titanium alloy, such as nitinol shape memory alloy. Typically,

stents 64 are sewn to graft 62 to thereby support graft 62. Stents 64 can be located either within (inside) or outside of a lumen defined by graft 62. Crown stent 68 is inside the lumen of graft 62 and supports proximal end 70 of graft 62. Clasping stent 72, is distal to crown stent 68, relative to the patient. Stent grafts can further include at least one hook or barb, not shown.

As shown in FIG. 7D, clasping stent 72 includes exposed proximal apices 73, 75, which are located within a lumen defined by graft 62. Proximal apices 73, 75, are dimensional for engagement with tines 42 of apex clasp 40, as shown in FIG. 7E. Referring to FIG. 7C, longitudinal support 74 extends along a major axis of stent graft 60 and is affixed to an outside surface of stent graft 60. As shown in FIG. 7F, longitudinal support 74 is on one side of a plane bisecting a major longitudinal axis of stent graft 60, that side being superior to any curve of control lumen 12 when stent graft 60 is secured by systems 10, 11, 13. Likewise, exposed proximal apices 73, 75 are on the side superior to a curve of control lumen 12 and are located proximal to a proximate end of longitudinal support 77. Further, longitudinal support 74 is substantially reverse-mirror symmetrical with respect to the major longitudinal axis of stent graft 60. A second side of stent graft 60 opposite to that which includes longitudinal support 74, is free of longitudinal support. Longitudinal support 74 at superior portion of stent graft 60 can assist in preventing collapse of the superior portion consequent to compliance by stent graft 62 to curvature of an aorta at a surgical site at an aneurysm, where stent graft 60 is to be deployed.

Typically, longitudinal support 74 is curved. Referring back to FIG. 7C, longitudinal support 74 has centerline 77 that is parallel to the longitudinal axis of stent graft 60. Longitudinal support 74, when curved, can be curved with respect to the centerline 77 in a manner that is about a mirror image of a portion of longitudinal support 74 on either side of a longitudinal plane of centerline 77, which is referred to herein as "reverse-mirror symmetrical."

In an embodiment, stent graft 60 can include longitudinal support 74 affixed, such as sewn, to the outside of graft 62, as shown in FIG. 7C. In another embodiment shown in FIG. 7K the longitudinal support is not present on graft 62.

As shown in FIG. 8, stent graft 60 includes at least one suture loop 76 on an inside surface of graft 62. Distal ends 26, 27 of supporting wires 22, 23 extend

through suture loops 76, whereby supporting wires 22, 23 can be released from suture loops 76 by proximal retraction of supporting wires 22, 23 toward the surgeon. Referring back to FIG. 7E, exposed proximal apices 73, 75 are secured to systems 11, 13 by tines 42 of apex clasp 40.

As can be seen in FIGS. 9A and 9B, inner sheath 80 is tapered between proximal end 82 and distal end 84, whereby the diameter of a lumen defined by inner sheath 80 is greater at distal end 84 than at proximal end 82. Further, inner sheath 80 is flared downwardly at inferior portion 83 of distal end 84. Further, the flared opening is asymmetric. Inferior portion 83 can be tapered distally as shown in FIG. 9A or straight relative to the most proximal end of inner sheath 84 as shown in FIG. 9B. As shown in FIG. 10, triangular piece 85 of inner sheath 80 is attached at inferior portion 83 of distal end 84. In an alternative embodiment, shown in FIGS. 11A and 11B, inner sheath 80 defines a distal opening that is not flared or is not asymmetric. Inner sheath 80 includes major longitudinal axis 87.

In another embodiment of the invention, shown in FIG. 12A, nose cone 18 defines proximal cavity 86 at a proximal end 87 of nose cone 18. Distal end 84 of inner sheath 80 can fit within proximal cavity 86, whereby retraction of inner sheath 80 from nose cone 18 releases distal end 84 of inner sheath 80 from proximal cavity 86.

Referring to FIG. 12B, radiopaque marker 88 is affixed to superior portion 90 of inner sheath 80. Inner sheath 80 has inferior portion 91. Sufficient partial deployment of stent graft 60 to finalize positioning of proximal end 70 of stent graft 60 at a surgical site will be indicated by alignment and, preferably, superimposing of radiopaque markers 78 and 88, as shown in FIG. 12C.

The inner sheath containing the stent graft, is constrained prior to delivery by introducer sheath 92, shown in FIG. 13. Nose cone 18 when fully retracted, forms an interference fit with distal end 94 of introducer sheath 92, thereby sealing the stent graft and inner sheath within introducer sheath 92 for delivery to a patient and within the patient to the surgical site where the stent graft is to be deployed. Introducer sheath 92 is, in turn, affixed to handle 96 of system 10, 11, 13, 100.

A method of the invention includes advancing introducer sheath 92, while nose cone 18 is fully retracted, and in interfering relation with introducer sheath 92,

endoluminally within an artery of a patient until nose cone 18 is proximate to a surgical site of a patient. Control lumen 12, outer control tube 30, pusher support tube 38, apex clasp 40, and sheath lumen 81 (FIGS. 5, *et seq.*), are all independently moveable from handle 96 (FIG. 13). The surgical site can be, for example, an aneurysm site 118 of, for example, an abdominal aorta, ascending aorta, a thoracic aorta or a descending aorta. As shown in FIGS. 14A-14E advancement of system 10, 11, 13 through an artery of a patient typically occurs by first introducing a guidewire through the aorta from a femoral artery of the patient (transfemoral access) to beyond the intended deployment site. Guidewire 20 extends through control lumen 12 of system 10, 11, 13. System 10, 11, 13 is then advanced along the guidewire until nose cone 18 and introducer sheath 92 are proximal, relative to the surgeon, of the surgical site, as shown in FIG. 14A. Nose cone 18, control lumen 12, pusher tube support 38, stent graft 60 and inner sheath 80 (FIG. 5, *et seq.*) are then all advanced beyond introducer sheath 92, until nose cone 18 and proximal end 70 of stent graft 60 are distal to the aneurysm, relative to the surgeon, as shown in FIG. 14B, at which point stent graft 60 and inner sheath 80 will no longer be constrained by introducer sheath 92. Instead, stent graft 60 will be constrained within inner sheath 80, which has a larger internal diameter than that of introducer sheath 92 once inner sheath 80 and stent graft 60 have been advanced beyond introducer sheath 92. Inner sheath 80 is then retracted relative to the remainder of system 10, 11, 13 as shown in FIG. 14C, wherein supporting wires 22, 23 (not shown) prevent rotation of inferior portion 5 of proximal end 4 of stent graft 60, also known as "retroflex." Supporting wires 22, 23 are then withdrawn by the merger, along with activation of apex clasp 40, if present, to release stent graft 60. Inner sheath 80 is then fully retracted to fully deploy stent graft 60, as shown in FIG. 14D. System 10, 11, 13 is then withdrawn through deploying stent graft 60, as shown in FIG. 14E. The same general method can be employed to deploy similar stent grafts at surgical sites other than the thoracic aorta or aortic arch, including, for example, the descending aorta or ascending aorta; or bifurcated stent grafts at the abdominal aorta.

More specifically, as can be seen in FIG. 15A, inner sheath 80 is then partially retracted relative to control lumen 12 and the pusher support tube to thereby

expose proximal end 70 of stent graft 60. Preferably, inner sheath 80 is retracted by retraction of sheath lumen 60 until the radiopaque marker 78 on stent graft 60 shifts from a position of non-alignment with radiopaque marker 88, as shown in FIG. 15C, to a position of alignment with radiopaque marker 88, as shown in FIG. 15E, a detail of which is shown in FIG. 15B. Upon this partial deployment of stent graft 60, supporting wires 22 prevent rotation of an inferior portion 5 of proximal end 70 of stent graft 60 in a generally longitudinal direction parallel to that of a major axis of control lumen 12 at proximal end 70 by providing resistance to that rotation through longitudinal restraint imposed by supporting wires 22 on suture loops 76 of stent graft 60.

In an embodiment, the stent graft and the inner sheath each include a radiopaque marker longitudinally aligned along a path of relative movement of the inner sheath and stent graft during deployment of the stent graft, and spaced apart from each other, whereby the partial retraction of the inner sheath will cause overlap of the radiopaque markers. The radiopaque markers are on superior portions of the inner sheath and the stent graft. In an embodiment, the radiopaque marker in the inner sheath is asymmetric, such as is D-shaped, wherein a straight portion of the D-shaped marker is aligned with a major longitudinal axis of the inner sheath. In an embodiment, the radiopaque marker of the stent graft is elongate and substantially aligned with the major longitudinal axis of the inner sheath.

Stent graft 60 can then be rotated about its major longitudinal axis or otherwise positioned by the surgeon by handle 96 (FIG. 13). Once proximal end 70 is properly positioned by the surgeon, apex clasp 40, if present, can be remotely activated by the surgeon to release exposed proximal apices 66 within stent graft 60 (FIG. 15D). Control lumen 12, pusher support tube 38 and sheath lumen 81 can then be retracted, separately or jointly (FIGS. 5A through 5E). Retraction of pusher support tube 38 will withdraw supporting wires 22 from suture loops 76. Continued retraction of control lumen 12, pusher support tube 38 and sheath lumen 81 will fully deploy stent graft 60 at the surgical site. System 10 can then be removed from the patient. The formation of a "bird's beak" is prevented by systems and methods of the invention. The apex clasp only partially clasps an inner stent, such as exposed proximal apices 73, 75 of clasping stent 72, and the proximal end of stent graft 60 is

initially deployed, then fully deployed as the inner sheath is retracted to thereby prevent formation of a "bird's beak."

In an alternative embodiment, system 11 or 13 lack supporting wires 22, 23, and fixing element 37. In this embodiment, a similar method described above would be employed to deploy stent graft 60, with the exception that supporting wires would not be present. At least one exposed proximal apex 73, 75 of clasping stent 72 would be engaged with tines 42 of apex clasp. In this embodiment, inner sheath 80 includes triangle piece 85, shown in FIG. 10. Further, this embodiment would be most suitable for implantation of stent graft 60 into a vessel, such as a blood vessel (*e.g.*, an artery) having an internal diameter of equal to or less than about 27 mm (*e.g.*, about 20 mm, about 22 mm, about 24 mm, about 26 mm, and 27 mm). Stent graft 60 in this embodiment typically would have an expanded external diameter in a range of between about 22 mm and about 30 mm (*e.g.*, about 25 mm).

In an alternative embodiment, shown in FIG. 16 wherein inner sheath 80 includes distal end 84 having a greater diameter than the remainder of inner sheath 80. Nose cone 18 defines proximal cavity 86, as can be seen in FIG. 17 following advancement of nose cone 18, stent graft 60 and inner sheath 80 beyond introducer sheath 92, inner sheath 80 is retracted by retracting sheath lumen 81 sufficient to release distal end 84 of inner sheath 80 from proximal cavity 86 of nose cone 18, as shown in FIG. 18. Proximal end 70 of stent graft 60 thereby expands to a constrained diameter equal to that of the internal diameter of distal end 84 of inner sheath 80. In one embodiment, not shown, radiopaque markers 78 and 88 overlap upon release of proximal end 70 of stent graft 60 from proximal cavity 86 of nose cone 18. Alternatively, inner sheath 80 includes second radiopaque marker 98, which overlaps radiopaque marker 78 of stent graft 60 upon release of proximal end 82 of inner sheath 80 from proximal cavity 86. In this embodiment, radiopaque marker 98 would be distal to radiopaque marker 88, and radiopaque markers 78 and 88 would overlap when sheath 80 is partially retracted from stent graft 60. The surgeon can then orient proximal end 70 of stent graft 60 prior to partial or complete deployment of stent graft 60. Where complete deployment follows, the presence of supporting wires 22 is optional.

Alternatively, following the release of distal end 84 of inner sheath 80 from proximal cavity 86, nose cone 18 is retracted within stent graft 60 by retraction of control lumen, as shown in FIGS. 19A through 19D. The surgeon can then further advance stent graft 60 and inner sheath, either without, or jointly with, nose cone 18, until proximal end 78 of stent graft 60 is properly positioned at the surgical site, such as by abutment or near abutment with an anatomical feature, such as a heart valve (e.g., aortic valve). Thereafter, sheath lumen 81 and inner sheath 80 can be retracted, either with or without retraction of nose cone 18, to at least partially deploy stent graft 60. In one embodiment, not shown, supporting wires 22 restrain an inferior portion of proximal ends 70 from rotating back toward the remainder of stent graft 60 in a direction generally longitudinal to a major axis of stent graft 60. Upon final positioning of proximal end 70, apices 66 are released from tines 42 of apex clasp 40 by remote retraction of tines 42 at handle 96, and system 11, 13 is retracted to fully deploy stent graft 60 at the surgical site. Alternatively, system 11, 13 is retracted to fully deploy stent graft 60 without use of supporting wires 22 or apex clasp 40.

In other embodiments, shown in FIGS. 20A and 20B, system 100 includes control lumen 102 to which is affixed nose cone 104. Outer control tube 106 extends about control lumen 102 but is not connected to nose cone 104. At least one supporting wire 108 is fixed to outer control tube 106. Supporting wire 108 extend substantially parallel to a major axis of control lumen 102 and are free at an end opposite to where it is fixed to outer control tube 106. Typically, free end 110 of supporting wire 108 is arcuate. Stent graft 60 is disposed about outer control tube 106 and about supporting wires 108. Inner sheath 112 is fixed to nose cone 104 and extends about stent graft 60. Optionally, stent graft 60 can be secured by an apex clasp (not shown), as discussed above, at proximal end 70 of stent graft 60. Control lumen 102, outer control tube 106 and an apex clasp, if present, can be controlled at handle 96 to which they are all connected. An introducer sheath (not shown) extends about inner sheath 112, stent graft 60, outer control tube 106 and control lumen 102, and is in interfering relation with nose cone 104 prior to deployment of inner sheath 112 and stent graft 60.

System 100 is particularly suitable for use where an endoluminal prosthesis is not implanted by directing the prosthesis through an femoral artery of a patient (transfemoral access), but alternatively introduced through the left ventricle of a patient's heart (transapical access). In this embodiment, introducer sheath 92, containing stent graft 60, is directed through the left ventricle of a patient's heart until stent graft 60 spans the diseased portion of an artery, such as an aneurysm at the ascending aorta. Control lumen 102 is then further advanced, thereby causing nose cone 104 to further advance and pull inner sheath 112 with it, thereby exposing and deploying stent graft 60. Supporting wires provide longitudinal resistance to prevent movement of stent graft 60 during deployment. Once stent graft 60 is fully exposed, or deployed, outer control tube 106 is advanced to release supporting wires from loops within stent graft 60, as described above. System 100 can then be retracted through stent graft 60 and removed from the patient.

In still another embodiment, shown in FIG. 21A, system 120 includes control lumen 122 having distal end 124 and nose cone 126 fixed at distal end 124. Stent graft 128 extends about control lumen 122. At least one suture 130 extends from nose cone 126 to proximal end 132 of stent graft 128, and from stent graft 128 to a fixed location 134 on control lumen 122. Suture 130 is releaseable from stent graft 128 by remote activation, whereby suture 130 separates from nose cone 126 to thereby deploy stent graft 128. In one embodiment, nose cone 126 includes longitudinal slot 133 at a distal end of suture 130 in interfering relation with slot 133, whereby increased tension in suture 130 causes suture 130 to come free of longitudinal slot 133 and, therefore, from nose cone 126. Further, suture 130 includes an expanded portion 131, such as knot, in interfering relation with the loop or the hole, not shown, whereby longitudinal movement of portion 130 of distal end 132 of stent graft 128 back toward the surgeon is prevented while distal end of suture 130 is in interfering relation with nose cone 126. When suture 130 is withdrawn from the longitudinal slot, suture can be withdrawn through the loop or the hole to thereby release proximal end 132 of stent graft 128. Apex clasp 136 is controlled by outer control tube 138. Alternatively, as shown in FIG. 21B, system 120 locks apex clasp 136 and outer control tube 138. The suture employed in the systems of FIGS. 21A and 21B can be a thread that includes a biocompatible

material, such as a suture gut, or a metal (e.g., wire) that includes stainless steel or a shape memory alloy.

In another embodiment, shown in FIGS. 22A and 22B, inner sheath 210 about stent graft 60 and extending from inner sheath liner 212 includes proximal perforated portion 214 that defines through-holes. The through-holes can be defined by a mesh or fabric of perforation portion 214 as shown in FIG. 22A or as distinct openings, such as longitudinal through-hole opening 216 shown in FIG. 22B, that extend substantially parallel to a major axis of inner sheath 210. Typically, the through-holes have a diameter equal to or greater than about 25 mm. The through-holes permit relatively continuous blood flow through stent graft 60 from aortic valve 218 through aortic arch 220 in the direction shown by arrows 222 during implantation of stent graft 60. Inner sheath of the invention defining through-holes can also be employed at other intended surgical sites, such as the mesenteric artery or the celiac artery.

Systems, stent grafts and delivery devices and components of systems, stent grafts and delivery devices as described in U.S. Application No. 10/784,462, filed on February 23, 2004; 10/884,136, filed on July 2, 2004; 11/348,176, filed on February 6, 2006; 11/353,927, filed on February 13, 2006; 11/449,337, filed on February 13, 2006; 11/699,700, filed on January 30, 2007; 11/699,701, filed on January 30, 2007; 11/700,609, filed on January 30, 2007; 11/700,510, filed on January 31, 2007; 11/701,867, filed on February 1, 2007; 11/828,675, filed on July 26, 2007; 11/828,653, filed on July 26, 2007; 12/137,592, filed on June 12, 2008; 11/701,876, filed on February 1, 2007; 61/164,545, filed on March 30, 2009; and 12/459,387, filed on June 30, 2009, the teachings of all of which are hereby incorporated by reference in their entirety, can be employed in the systems, stent grafts and delivery devices described herein.

The teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety.

Equivalents

While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A system for implanting a prosthesis, comprising:

   a) a control lumen;

   b) a nose cone fixed at a distal end of the control lumen; and

   c) at least one supporting wire fixed at one end and substantially parallel to a major axis of the control lumen and free at an opposite end, wherein the free end of at least one of the supporting wires is arcuate.

2. The system of claim 1, further including at least one stop, having a diameter greater than that of the supporting wire, proximate to the free end of the supporting wire.

3. The system of claim 1, further including an outer control tube slideable along the control lumen, wherein the supporting wire is fixed at one end to the outer control tube.

4. The system of claim 3, wherein the supporting wire is fixed at one end to the outer control tube proximal to the nose cone and the free end is distal to the fixed end and is proximate to the nose cone.

5. The system of claim 4, further including an apex clasp at an end of the outer control tube and slideable along the control lumen with movement of the outer control tube.

6. The system of claim 5, further including a stent graft extending about the outer control tube and the supporting wires, the stent graft including a proximal end at the clasp and a distal end that is proximal to the clasp.

7. The system of claim 6, wherein the stent graft includes at least one clasp stent defining at least one exposed portion that is releasably secured to the clasp.

8. The system of claim 7, wherein the stent graft includes for each supporting wire, a loop within the stent graft that releasably secures the free end of each respective supporting wire.

9. The system of claim 8, wherein the stent graft includes a crown stent at the proximate end of the stent graft.

10. The system of claim 9, wherein the crown stent is secured to an interior portion of a graft portion of the graft stent.

11. The system of claim 10, wherein the crown stent is between the clasp stent and the proximal end of the graft stent.

12. The system of claim 1, further including a pusher support tube distal or proximal to the fixed end of the supporting wires and slideable along the control lumen.

13. The system of claim 12, further including an outer control tube slideable along the control lumen, wherein the supporting wire is fixed at one end to the outer control tube.

14. The system of claim 13, further including an apex clasp at an end of the outer control tube and slideable along the control lumen with movement of the outer control tube.

15. The system of claim 6, wherein the stent graft is a bifurcated stent graft.

16. The system of claim 6, wherein the stent graft further includes at least one radiopaque marker.

17. The system of claim 15, wherein the bifurcated stent graft further includes at least one radiopaque marker.

18. The system of claim 1, wherein the supporting wire is formed of at least one member selected from the group consisting of a metal, an alloy and a polymer.

19. The system of claim 18, wherein the metal includes stainless steel.

20. The system of claim 18, wherein the alloy includes a shape memory alloy.

21. The system of claim 20, wherein the shape memory alloy includes a nickel titanium alloy.

22. The system of claim 1, wherein the system includes at least two supporting wires.

23. The system of claim 22, wherein the system includes two supporting wires.

24. The system of claim 23, wherein the free ends of the supporting wires each include a bulbous tip.

25. The system of claim 24, wherein each of the supporting wires is cantilevered.

26. The system of claim 25, further including a sheath lumen that is slideable along the outer catheter proximal to the supporting wires.

27. The system of claim 26, further including an inner sheath extending distally from the sheath lumen.

28. The system of claim 27, wherein the inner sheath includes at least one through-hole at a proximal end of the inner sheath.

29. The system of claim 27, wherein the inner sheath includes at least one radiopaque marker.

30. The system of claim 29, wherein at least one radiopaque marker is located on the inner sheath facing away from a concavity of a curve defined by the control lumen and the radiopaque marker of the inner sheath overlaps at least

one radiopaque mark of the stent graft when the stent graft is partially deployed.

31. The system of claim 30, wherein the inner sheath defines a flared opening at a distal end of the inner sheath.

32. The system of claim 31, wherein the flared opening is asymmetric.

33. The system of claim 32, wherein the control lumen is arcuate.

34. The system of claim 33, wherein the supporting wires are clustered within a curve defined by the control lumen.

35. The system of claim 34, wherein the supporting wires are connected at a concavity of the outer control tube.

36. The system of claim 33, wherein a major portion of the flared opening of the inner sheath is within the curve defined by the control lumen.

37. The system of claim 36, wherein the flared opening faces a concavity of the curve defined by the control lumen.

38. The system of claim 1, wherein the supporting wire is fixed to the outer control tube proximate to the nose cone, and wherein the free end of the supporting wire is proximal to the fixed end.

39. The system of claim 38, further including an inner sheath that is fixed to the nose cone and extends proximally from the nose cone about the supporting wire.

40. The system of claim 39, further including a stent graft extending about the control lumen and supporting wire and within the inner sheath.

41. The system of claim 40, wherein the stent graft includes a loop within the stent graft that releasably secures the free end of each respective supporting wire.

42. The system of claim 41, wherein the free end of at least one supporting wire is arcuate.

43. The system of claim 42, further including at least one stop, having a diameter greater than that of the supporting wire, proximate to the free end of the supporting wire.

44. The system of claim 42, wherein the loop releasably secures the free end of each respective supporting wire between the free end and the stop, whereby movement of the loop along the supporting wire is restricted.

45. The system of claim 1, further including an inner sheath, and wherein the nose cone defines a proximal cavity into which a distal portion of the inner sheath fits, whereby relative motion of the nose cone and inner sheath releases the distal end of the inner sheath from the cavity.

46. The system of claim 45, wherein the nose cone is retractable within the inner sheath after release of the inner sheath.

47. The system of claim 46, further including a stent graft within the inner sheath, inner sheath and the nose cone are retractable relative to the stent graft.

48. The system of claim 46, whereby the stent graft is deployed by joint retraction of the inner sheath and the nose cone.

49. The system of claim 47, wherein the stent graft includes a loop inside the stent graft that releasably secures a respective supporting wire, whereby movement of the loop along the supporting wire is restricted.

50. A system for implanting a prosthesis, comprising;

a) a control lumen;

b) a nose cone fixed at a distal end of the control lumen;

c) a stent graft extending about the control lumen; and

d) at least one suture extending from the nose cone to a proximal end of the stent graft, and from the stent graft to a fixed location on the control lumen, said suture being releasable from the stent graft by remote activation.

51. A system for implanting a prosthesis, comprising:

a) a control lumen;

b) a nose cone fixed at a distal end of the control lumen; and

c) an inner sheath extending about the control lumen that defines a distal opening at a distal end of the inner sheath, wherein the nose cone is retractable within the inner sheath.

52. The system of claim 51, further including an introducer sheath about the inner sheath, wherein the introducer sheath is retractable relative to the inner sheath to thereby release the distal end of the inner sheath, and whereby the nose cone can thereafter be retracted within the inner sheath.

53. The system of claim 52, further including a stent graft extending with the inner sheath and about the external lumen.

54. The system of claim 53, wherein the inner sheath is retractable relative to the nose cone.

55. The system of claim 54, wherein the inner sheath includes at least one through-hole at a proximal end of the inner sheath.

56. The system of claim 51, wherein the nose cone defines a cavity with which the distal end of the inner sheath can fit, and which will release the distal end upon retraction of the inner sheath relative to the nose cone.

57. The system of claim 51, further including at least one supporting wire fixed at one end and substantially parallel to a major axis of the control lumen and

free at an opposite end, wherein the free end of at least one of the supporting wires is arcuate and wherein the stent graft includes a loop inside the stent graft that releasably secures at least one supporting wire, whereby movement of the loop along the supporting wire is restricted.

58. A method for implanting a prosthesis, comprising the steps of:

a) delivering a stent graft through an artery to an aneurysm site of a patient, the stent graft being radially constrained by an inner sheath and supported at least in part by a control lumen, the stent graft further being longitudinally constrained by at least one supporting wire extending from a nose cone, from the control lumen or from an outer control tube extending about and slideable along the control lumen, wherein the free end of at least one of the supporting wires is arcuate and extends through a loop within a proximal end of the stent graft;

b) partially retracting the inner sheath from the stent graft, whereby the supporting wire at least partially restricts longitudinal movement of the proximal end of the stent graft until the proximal end of the stent graft is secure within the artery to thereby prevent rotation of a portion of the proximal end of the stent graft at an inferior portion of the artery;

c) retracting the inner sheath; and

d) retracting the supporting wire, thereby removing the supporting wire from the loop and deploying the stent graft within the artery at the aneurysm site in the patient.

59. The method of claim 58, wherein the control lumen and the supporting wire are retracted jointly.

60. The method of claim 59, wherein the inner sheath and supporting wire are jointly retracted.

61. The method of claim 58, wherein the supporting wire has at least one stop, the stop limiting movement of the loop along the supporting wire.

62. The method of claim 58, wherein the stent graft and the inner sheath each include a radiopaque marker longitudinally aligned along a path of relative movement of the inner sheath and stent graft during deployment of the stent graft, and spaced apart from each other, whereby the partial retraction of the inner sheath will cause overlap of the radiopaque markers.

63. The method of claim 62, wherein the radiopaque markers are on superior portions of the inner sheath and the stent graft.

64. The method of claim 63, wherein the radiopaque marker in the inner sheath is asymmetric, wherein a shape of the marker changes as the marker is aligned with a major longitudinal axis of the inner sheath.

65. The method of claim 64, wherein the radiopaque marker of the stent graft is elongate and substantially aligned with the major longitudinal axis of the inner sheath.

66. The method of claim 58, wherein the inner sheath is releasably secured at a distal end within a cavity defined by a proximal end of the nose cone, and further including the steps of:

a) partially retracting the inner sheath to release said distal end of the inner sheath from the nose cone and thereby cause partial deployment of the stent graft;

b) at least partially retracting the nose cone to within the stent graft;

c) advancing the stent graft to a final position within the artery; and

d) jointly retracting the inner sheath, the nose cone and the supporting wires to fully deploy the stent graft within the artery at the aneurysm site in the patient.

67. The method of claim 66, wherein the inner sheath defines at least one through hole at a proximal end of the inner sheath.

68. The method of claim 58, wherein at least the stent graft is further constrained at at least one end by a clasp, and further including the step of releasing the clasp prior to retraction of the supporting wire from the loop in the graft stent.

69. The method of claim 58, wherein the stent graft further includes at least one radiopaque marker.

70. The method of claim 69, wherein the radiopaque marker is located on the stent graft facing away from a concavity of a curve defined by the control lumen.

71. The method of claim 70, wherein the inner sheath further includes at least one radiopaque marker.

72. The method of claim 71, wherein the radiopaque marker of the inner sheath is located on the inner sheath facing away from the concavity of the curve defined by the control lumen and the radiopaque marker of the inner sheath overlaps at least one radiopaque marker of the stent graft when the stent graft is partially deployed.

73. The method of claim 58, wherein the stent graft is further constrained by a pusher support tube distal or proximal to the fixed end of the supporting wire.

74. The method of claim 58, wherein the aneurysm site is an abdominal aorta.

75. The method of claim 58, wherein the aneurysm site is in an ascending aorta.

76. The method of claim 58, wherein the aneurysm site is a thoracic aorta.

77. A method for implanting a prosthesis, comprising the steps of:

a) delivering a stent graft through an artery to an aneurysm site in a patient, the stent graft being radially constrained by an inner sheath and supported at least in part by a control lumen, the stent graft further being constrained by at least one suture extending from a nose cone at a distal end of the control lumen to a proximal end of the stent graft extending to a fixed location on the control lumen, the suture being releasable from the nose cone and the stent graft by remote activation;

b) partially retracting the inner sheath from the stent graft, whereby the suture at least partially restricts longitudinal movement of the proximal end of the stent graft until the proximal end of the stent graft is secure within the artery, thereby preventing rotation of a portion of the proximal end of the stent graft at an inferior portion of the artery;

c) activating the suture, whereby the suture is released from the nose cone and releases the stent graft; and

d) retracting the inner sheath to thereby deploy the stent graft within the artery at the aneurysm site of the patient.

78. The method of claim 77, wherein the aneurysm site is an abdominal aorta.

79. The method of claim 77, wherein the aneurysm site is in an ascending aorta.

80. The method of claim 77, wherein the aneurysm site is a thoracic aorta.

81. The method of claim 77, wherein the aneurysm site is a descending aorta.

82. A system for implanting a prosthesis, comprising:

a) a control lumen;

b) a nose cone fixed at a distal end of the control lumen;

c) a sheath lumen extending about the control lumen and slideable along the control lumen; and

d) an inner sheath extending distally from the sheath lumen and about the control lumen between the nose cone and the sheath lumen, the inner sheath defining at least one through-hole at a proximal end of the inner sheath proximate to the sheath lumen.

83. The system of claim 81, wherein the through-holes are defined by a mesh of the inner sheath.

84. The system of claim 82, wherein the through-holes are elongate, having a major axis substantially parallel to a major axis of the inner sheath.

85. A system for implanting a prosthesis, comprising:

a) a control lumen;

b) a nose cone fixed at a distal end of the control lumen;

c) an outer control tube extending about the control lumen;

d) an apex clasp at a distal end of the outer control tube and slideable along the control lumen;

e) a sheath lumen extending about the outer control tube;

f) an inner sheath extending distally from the sheath lumen about the outer control tube, the inner sheath including a triangular piece at a distal end of the inner sheath; and

g) a stent graft between the outer control tube and the inner sheath, the stent graft including a proximal end proximate to the nose cone having a clasping stent at the proximal end, wherein the clasping stent has at least one exposed proximal apex releasably held by the apex clasp.

86. The system of claim 85, wherein the control lumen is arcuate, being a superior side, an inferior side, and wherein the triangular piece of the inner sheath is at the inferior side of the control lumen.

87. The system of claim 85, wherein the stent graft further includes a crown stent.

88. The system of claim 85, wherein the inner sheath includes at least one through-hole at a proximal end proximate to the sheath lumen.

89. A method for implanting a prosthesis, comprising the steps of:

a) delivering a stent graft through an artery to a point distal, relative to the patient, of an aneurysm site of a patient, the stent graft being radially constrained by an inner sheath, and affixed to an outer control tube, and wherein the inner sheath is constrained by an introducer sheath, the stent graft and the inner sheath each including at least one radiopaque marker on superior portions of the stent graft and the inner sheath, the radiopaque markers being separated along a major longitudinal axis of the inner sheath;

b) advancing the inner sheath, the stent graft and the outer control lumen beyond the introducer sheath until the stent graft spans the aneurysm site of the patient;

c) partially retracting the inner sheath from the stent graft, whereby the radiopaque marker of the stent graft overlaps to the radiopaque marker of the inner sheath;

d) positioning a proximal end of the stent graft within the artery; and

e) fully retracting the inner sheath to thereby fully deploy the stent graft within the artery.

90. The method of claim 89, wherein the radiopaque marker of the inner sheath is asymmetric.

91. The method of claim 90, wherein the asymmetric marker is D-shaped.

92. The method of claim 89, wherein the radiopaque marker of the stent graft is an elongate-shape.

93. The method of claim 89, wherein the inner sheath defines a flared opening at a distal end of the inner sheath.

94. The method of claim 93, wherein the flared opening is asymmetric.

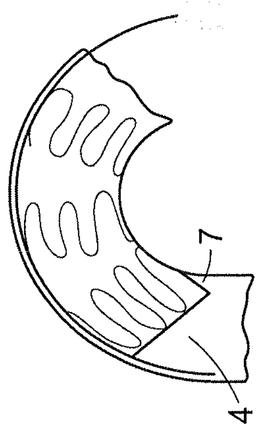

FIG. 3
Prior Art

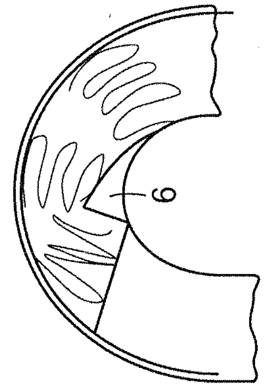

FIG. 4
Prior Art

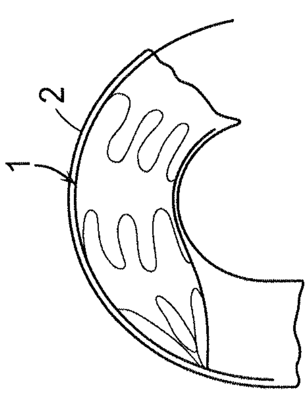

FIG. 1
Prior Art

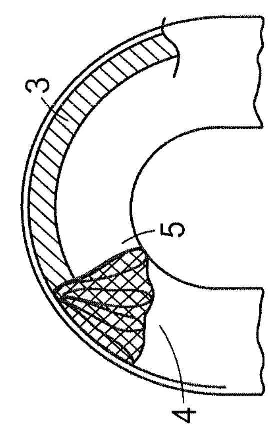

FIG. 2
Prior Art

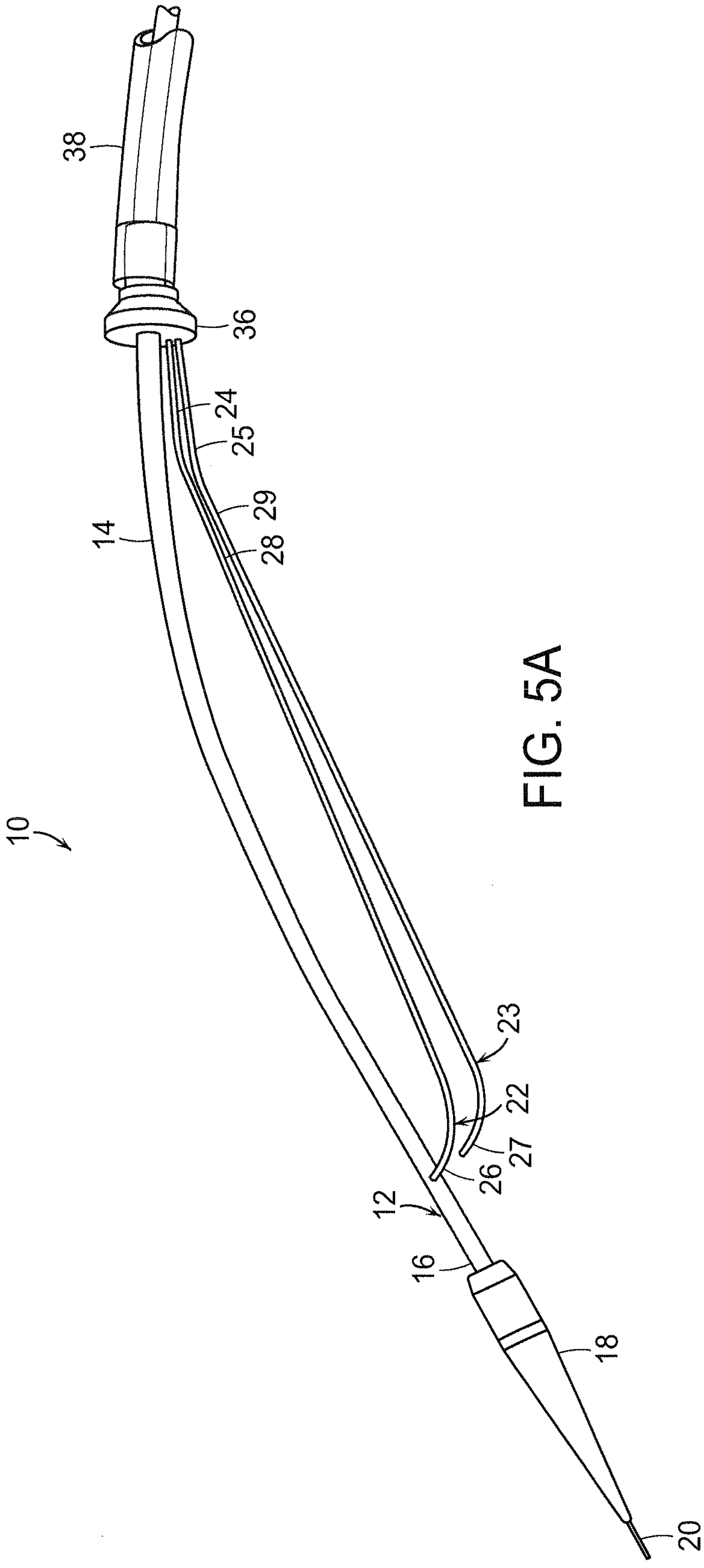

FIG. 5A

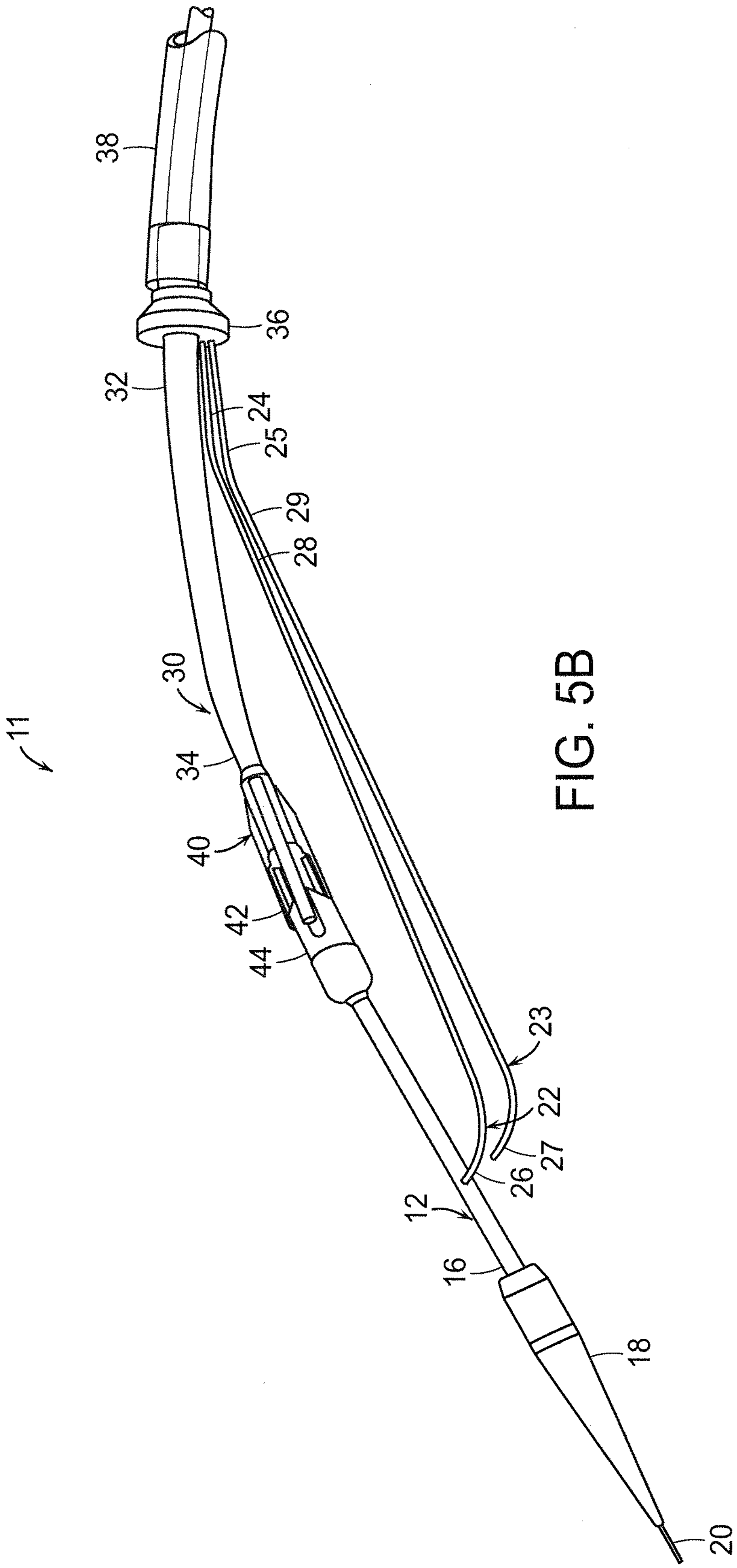

FIG. 5B

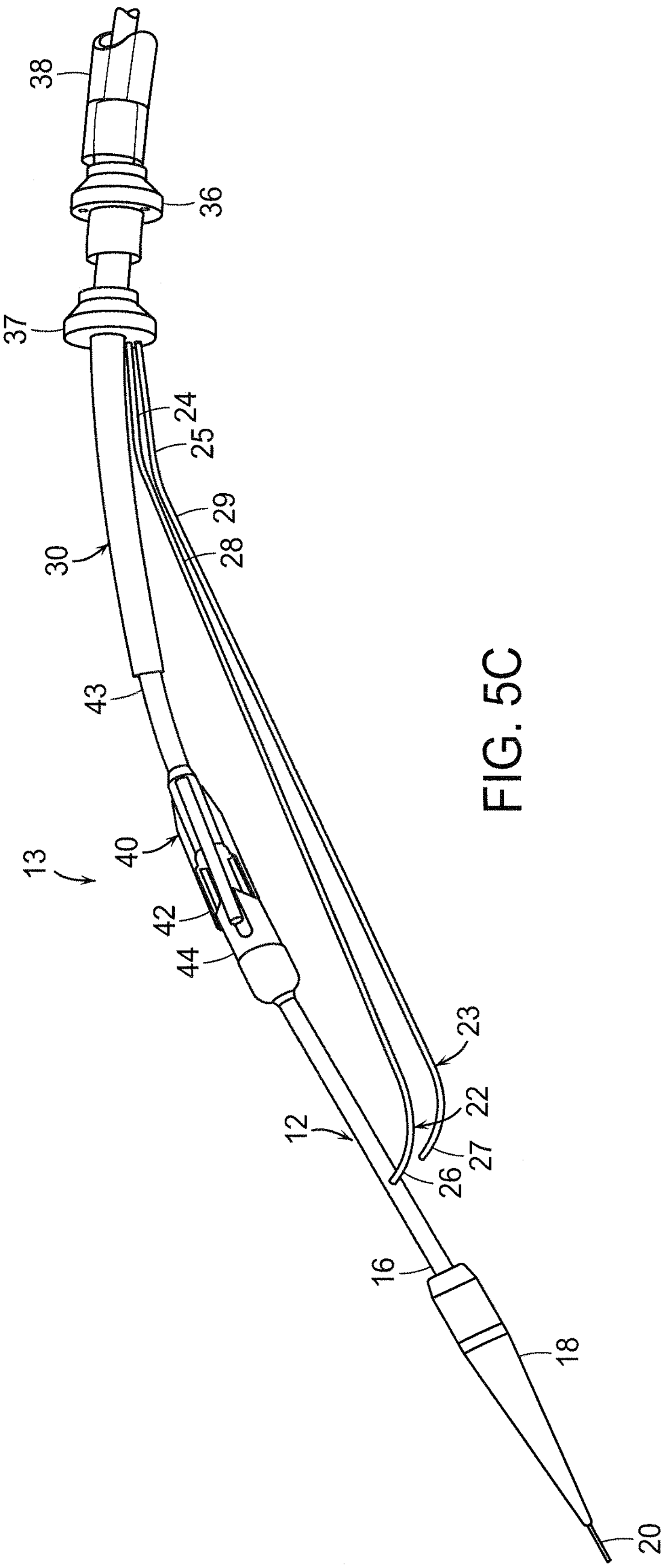

FIG. 5C

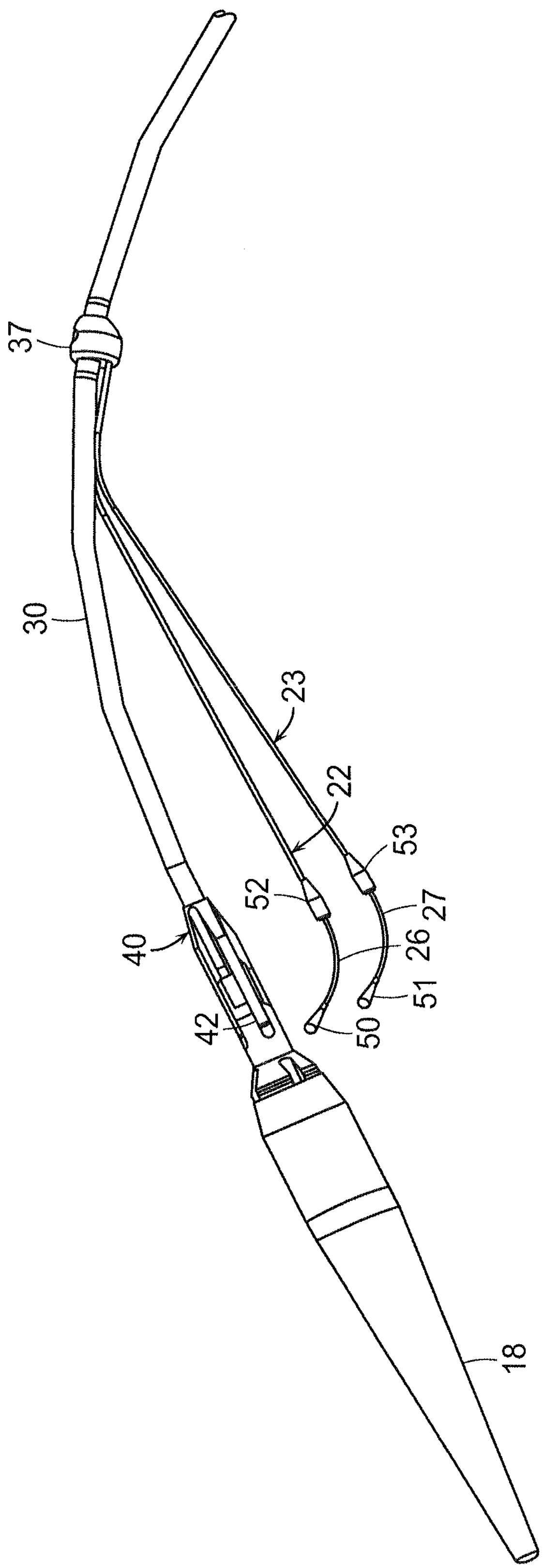

FIG. 6

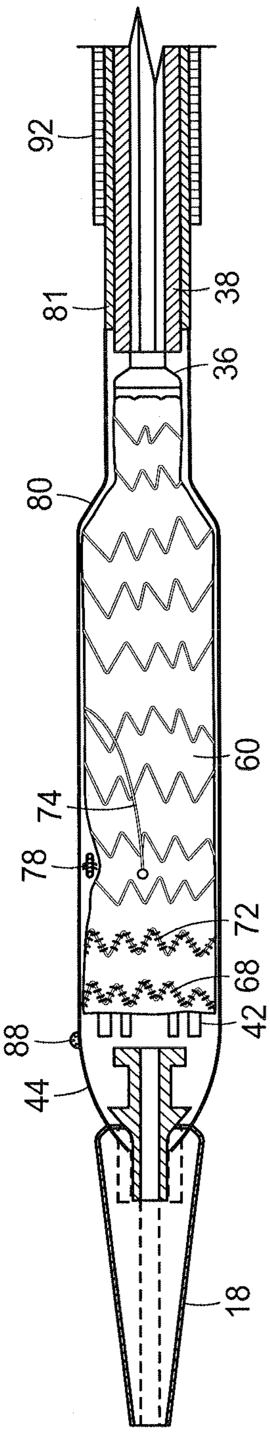

FIG. 7A

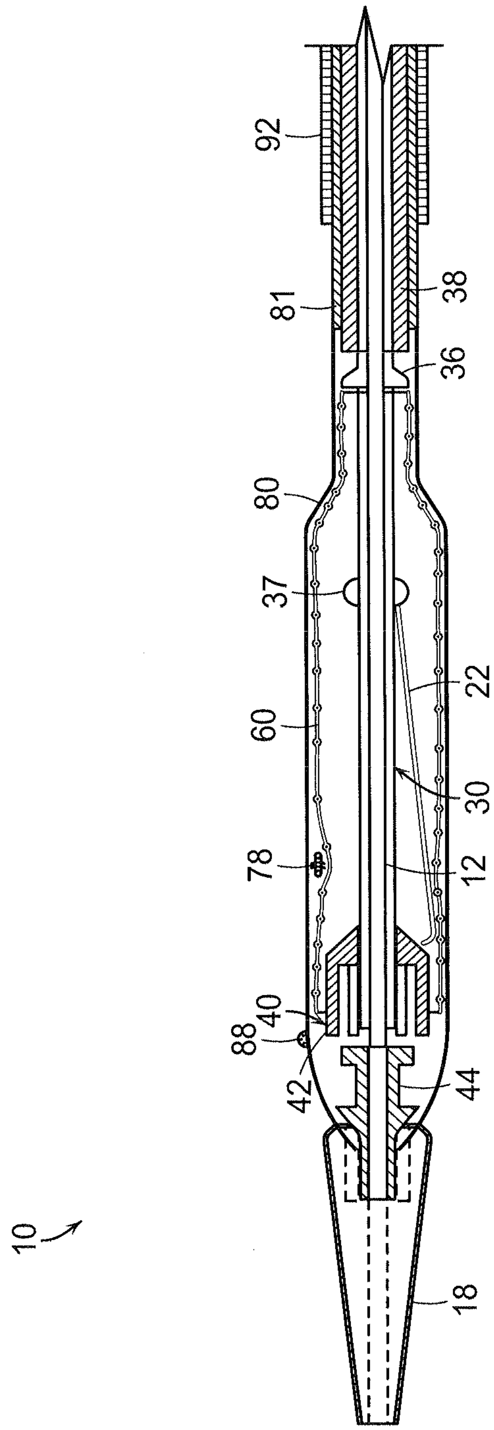

FIG. 7B

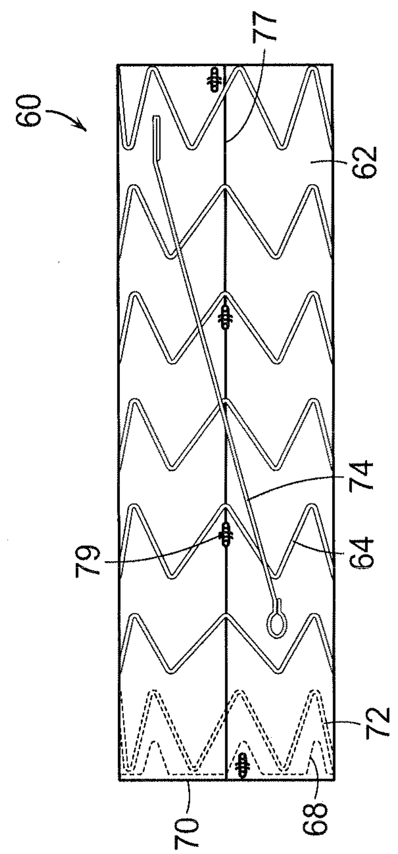

FIG. 7C

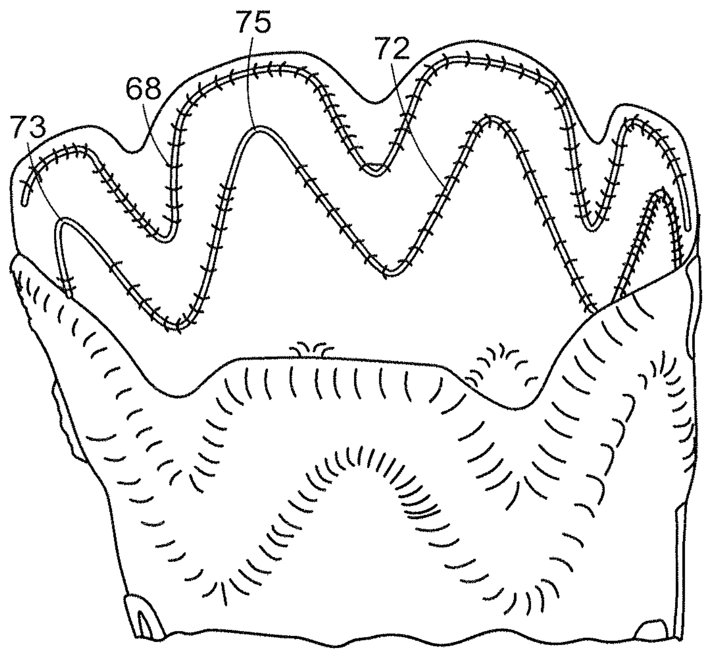

FIG. 7D

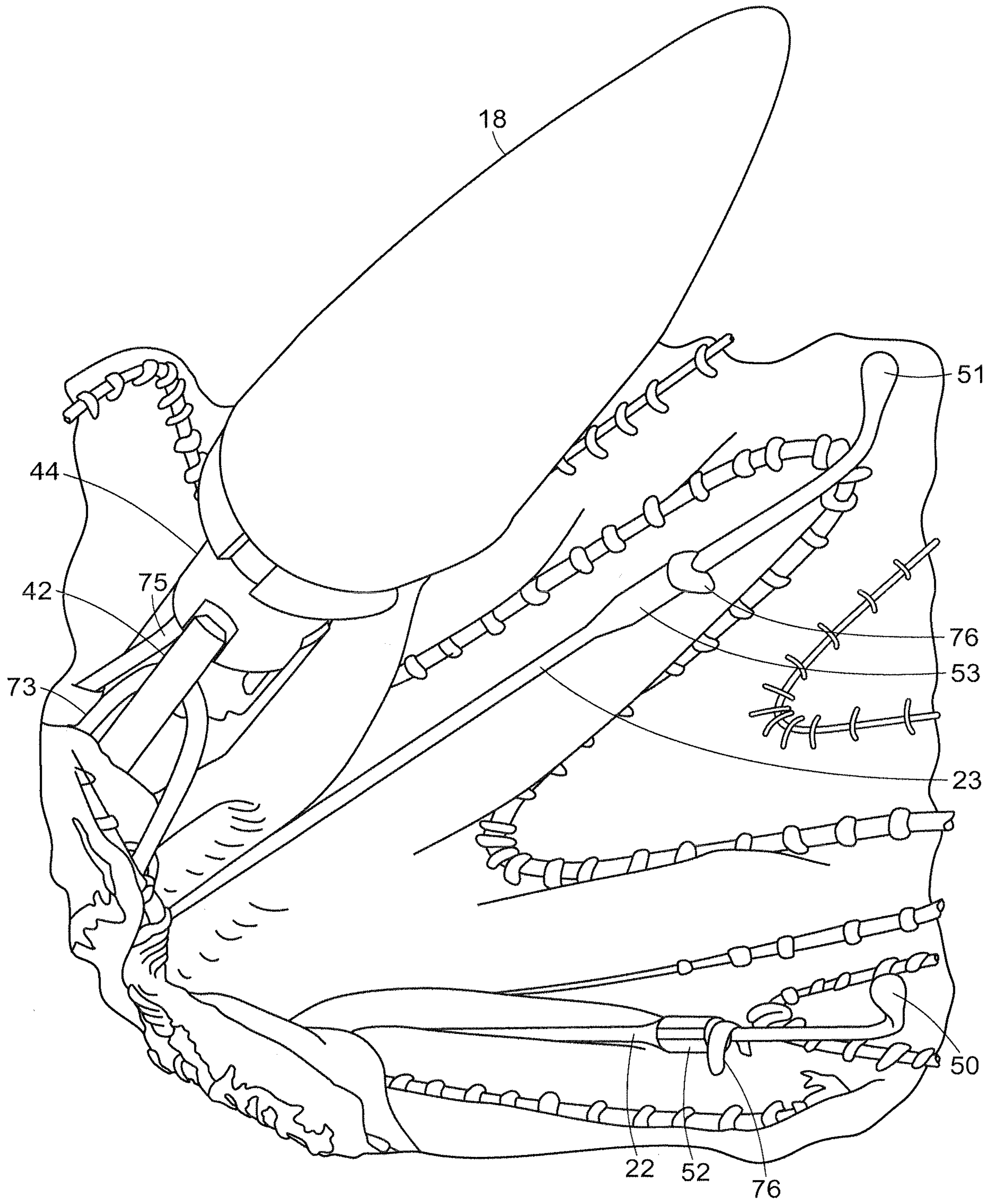

FIG. 7E

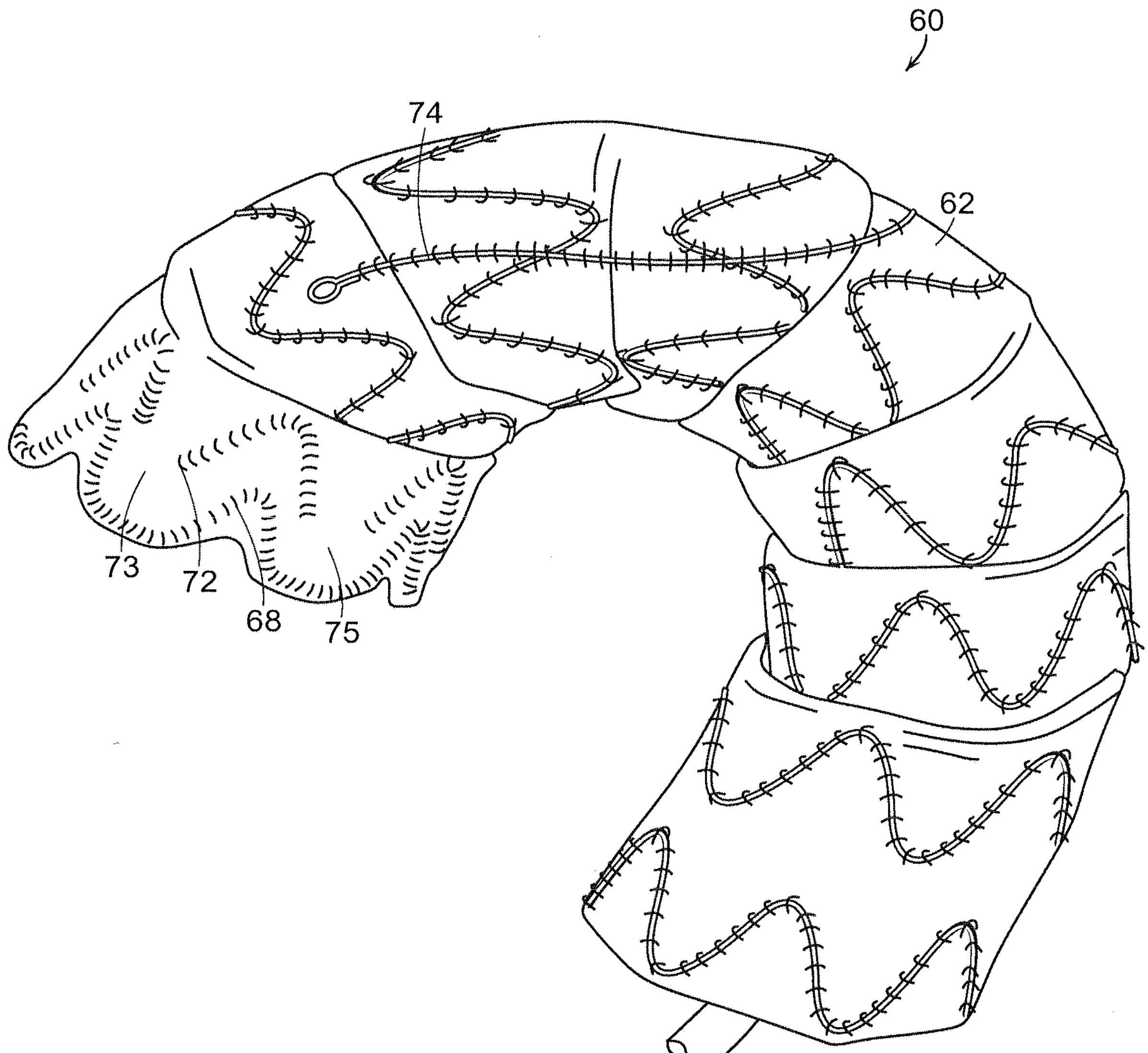

FIG. 7F

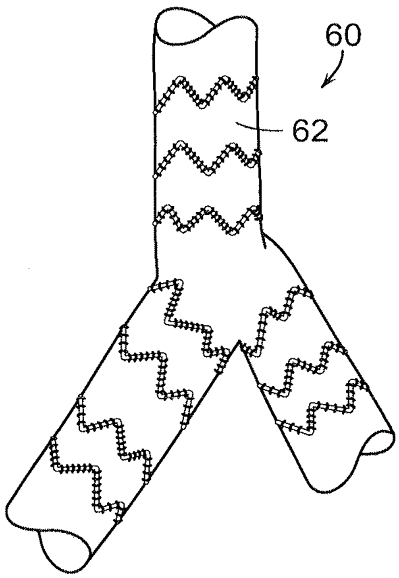

FIG. 7H

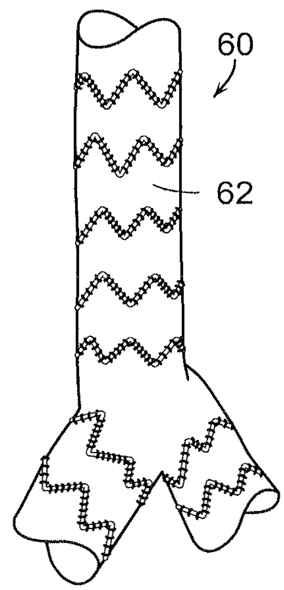

FIG. 7I

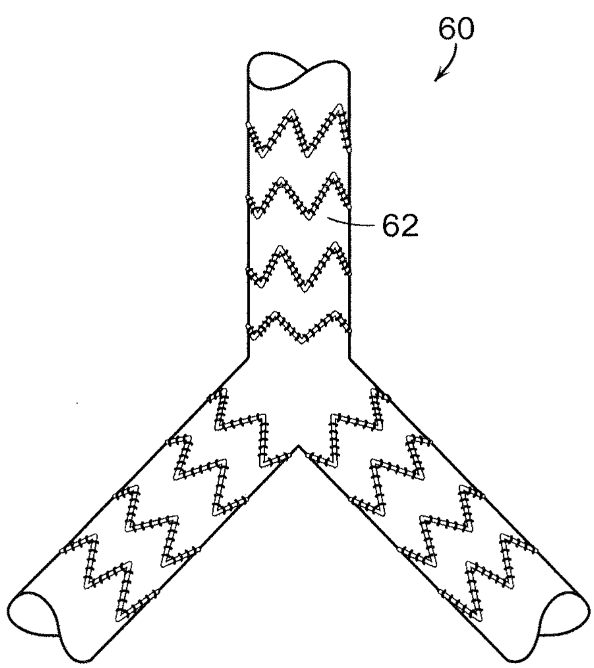

FIG. 7G

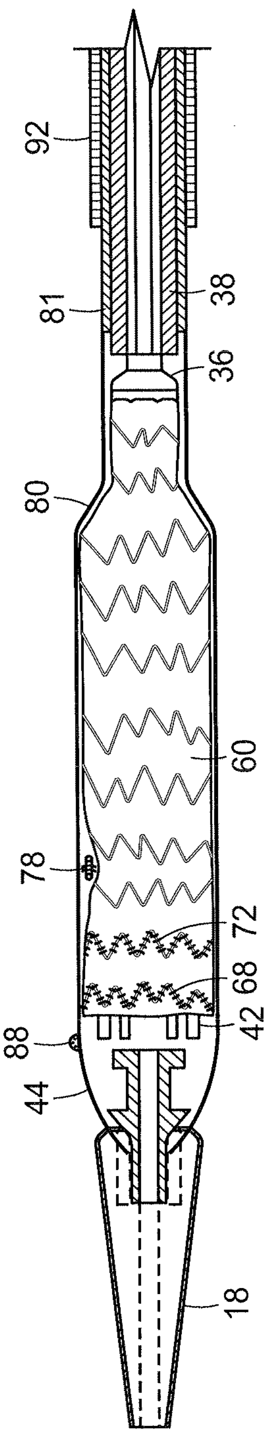

FIG. 7J

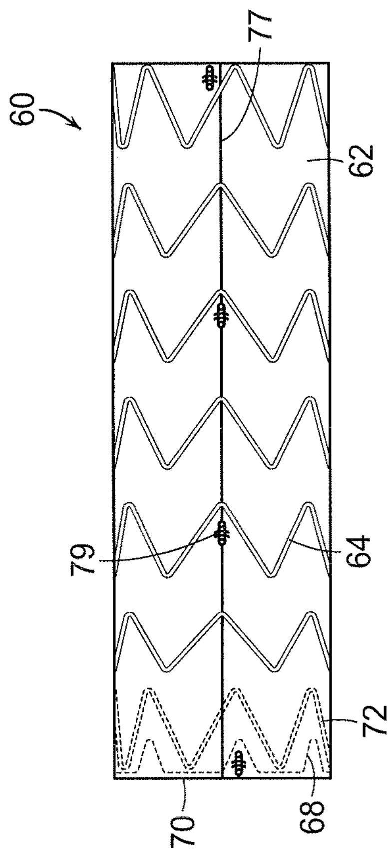

FIG. 7K

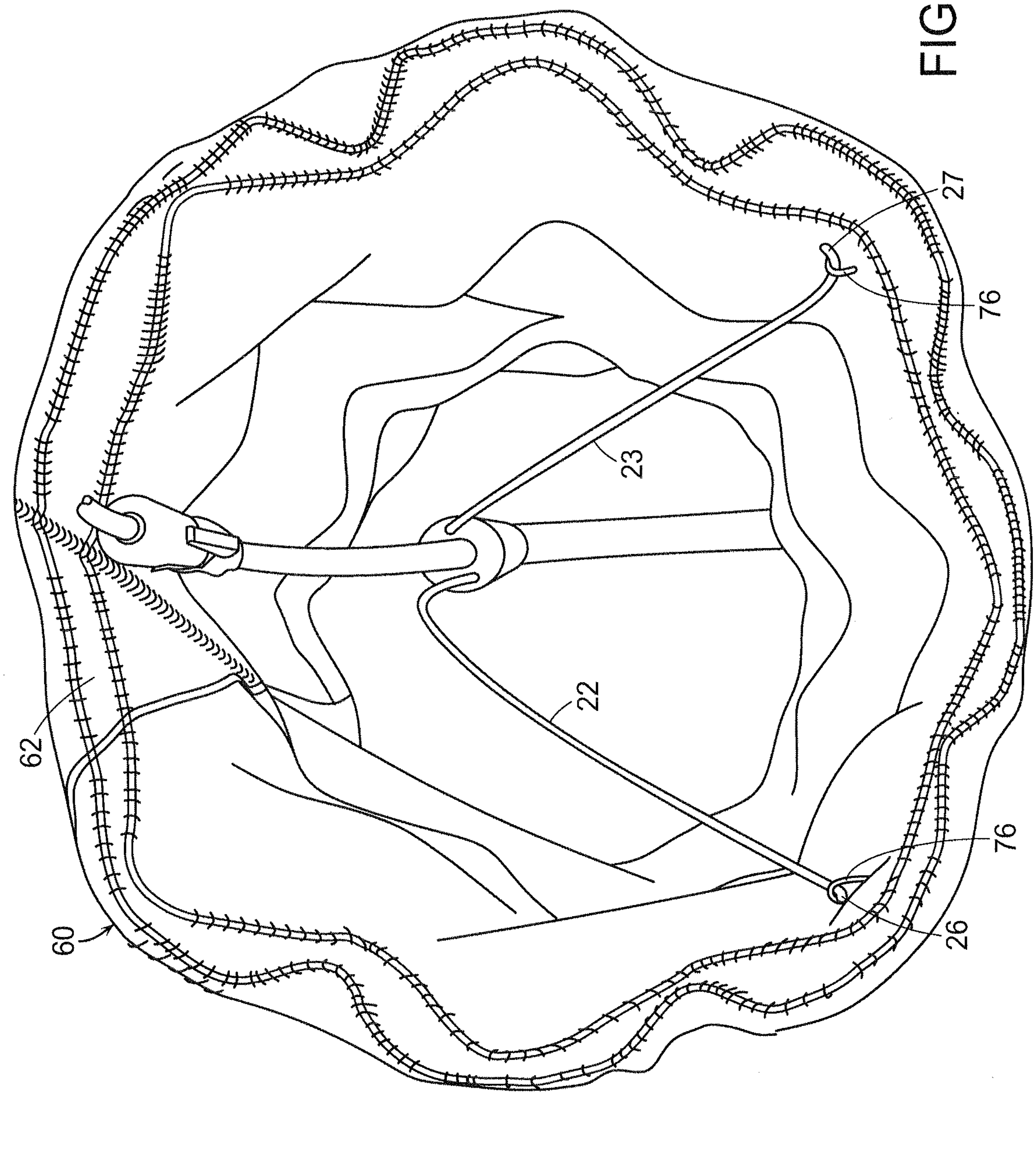

FIG. 8

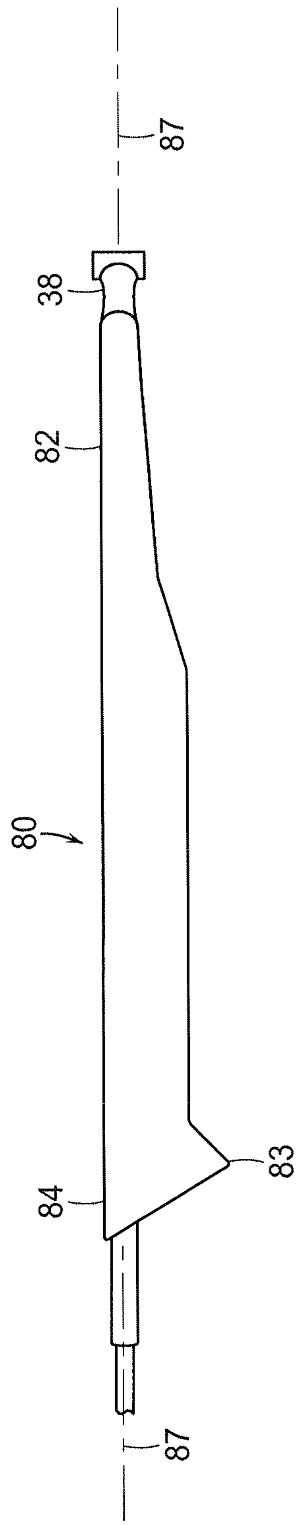

FIG. 9A

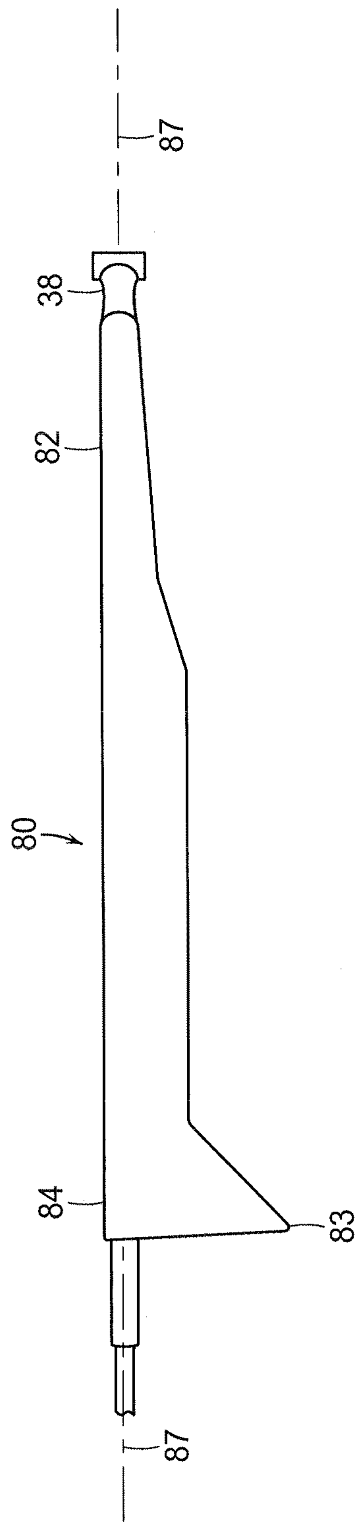

FIG. 9B

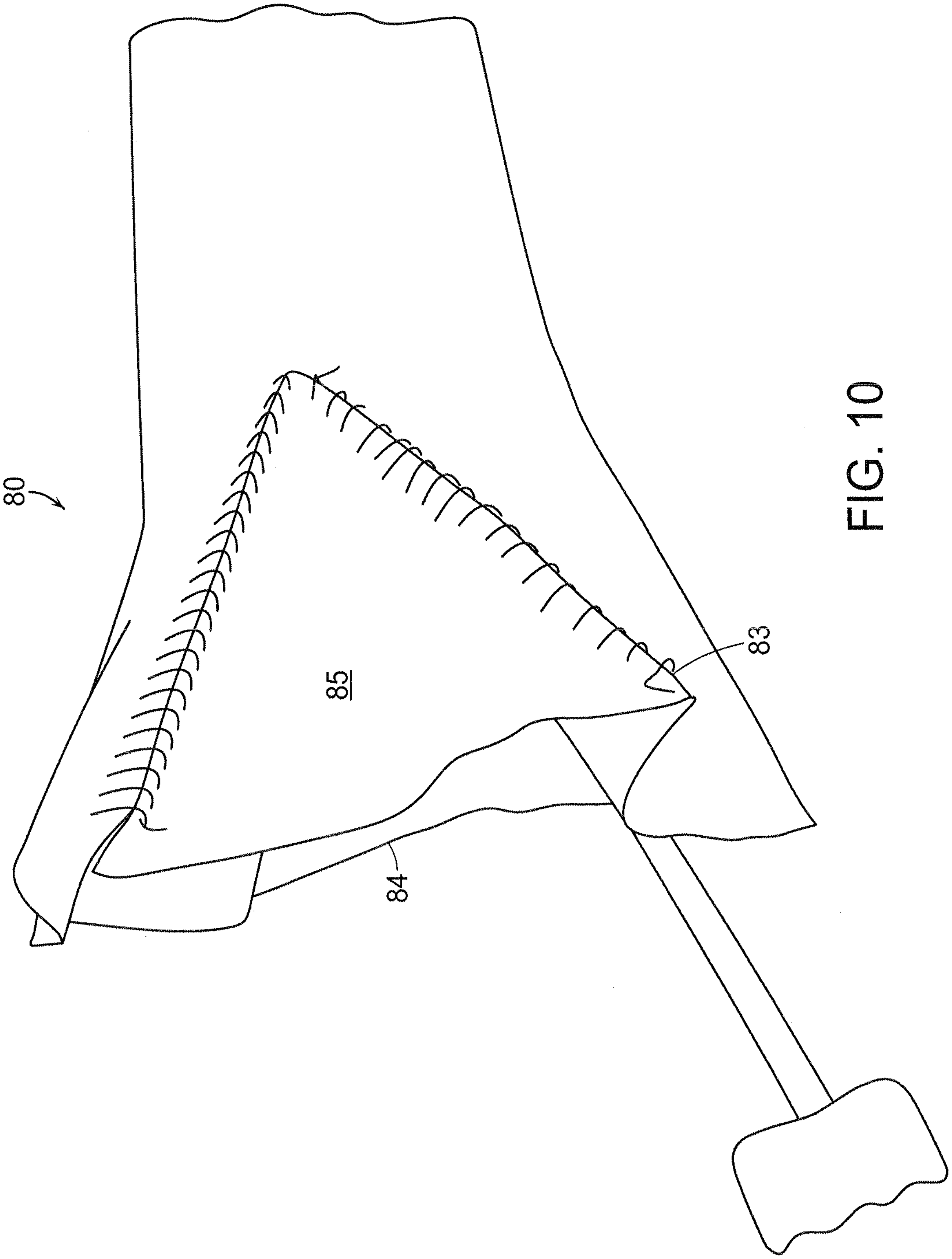

FIG. 10

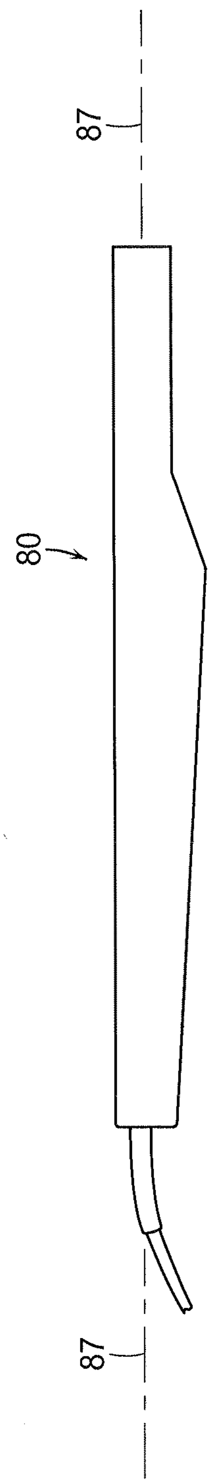

FIG. 11A

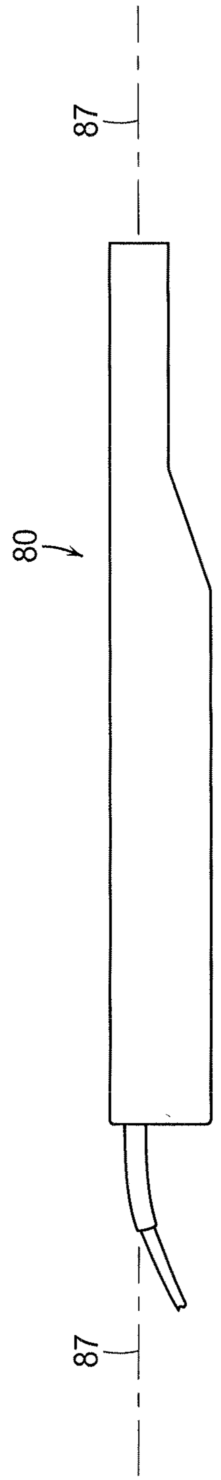

FIG. 11B

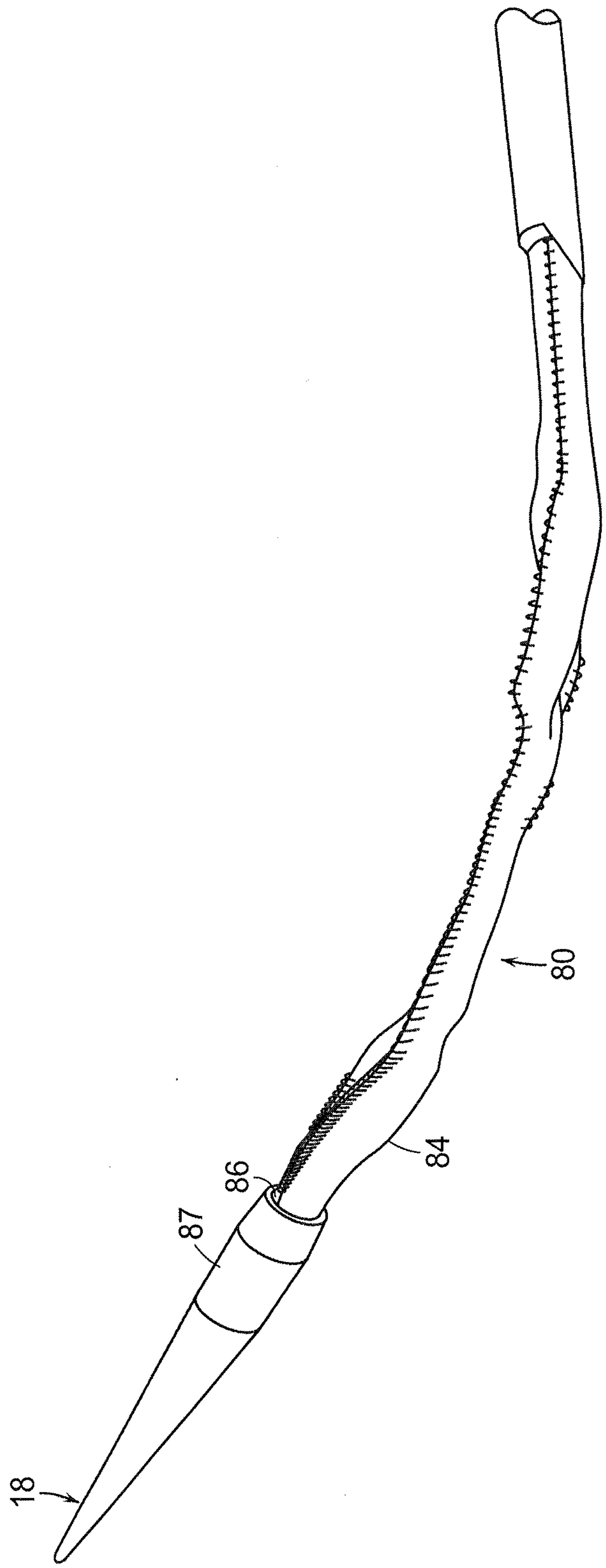

FIG. 12A

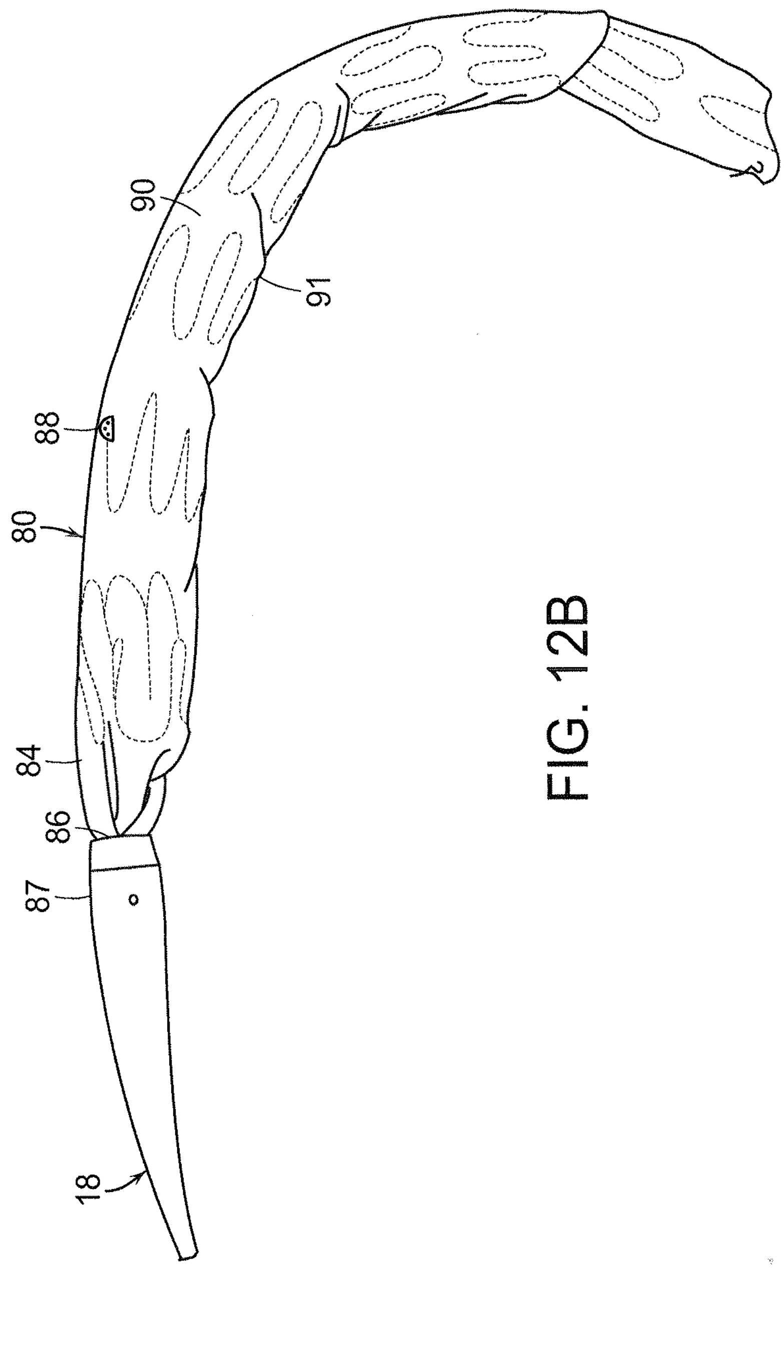

FIG. 12B

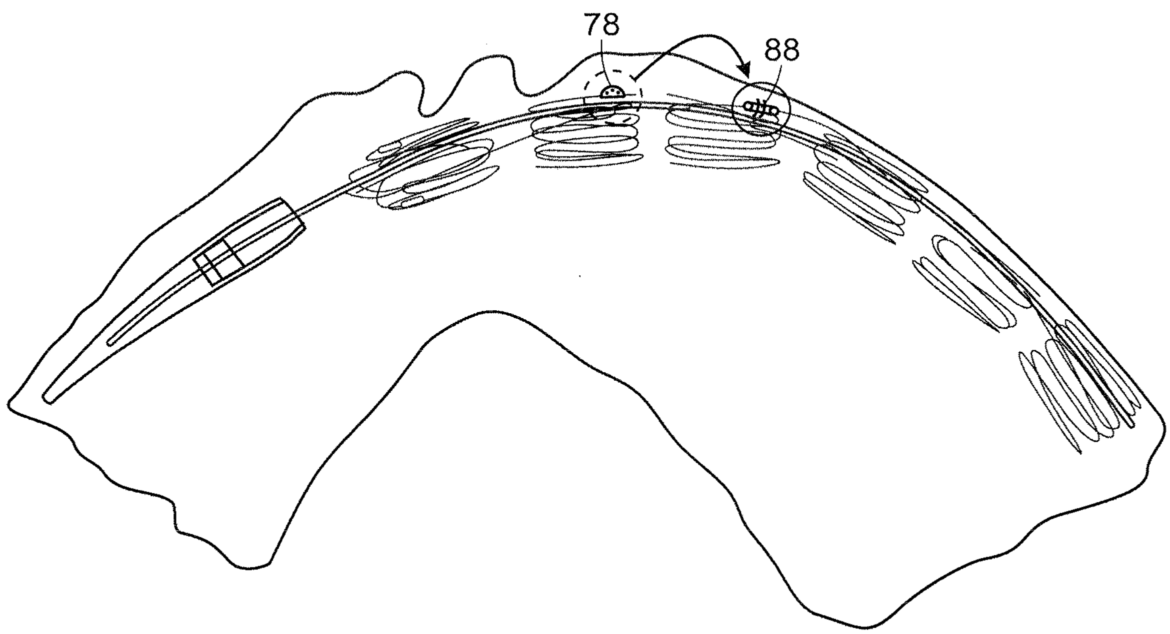

FIG. 12C

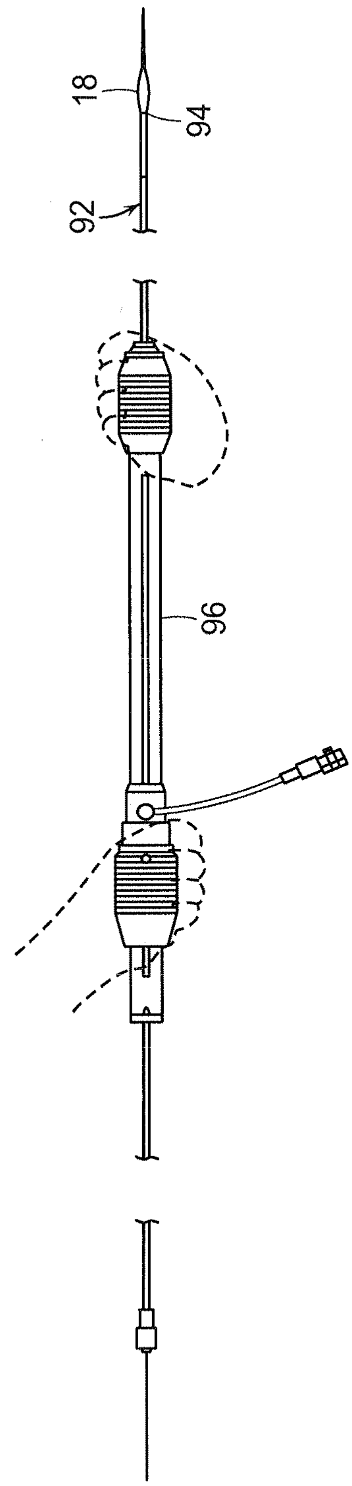

FIG. 13

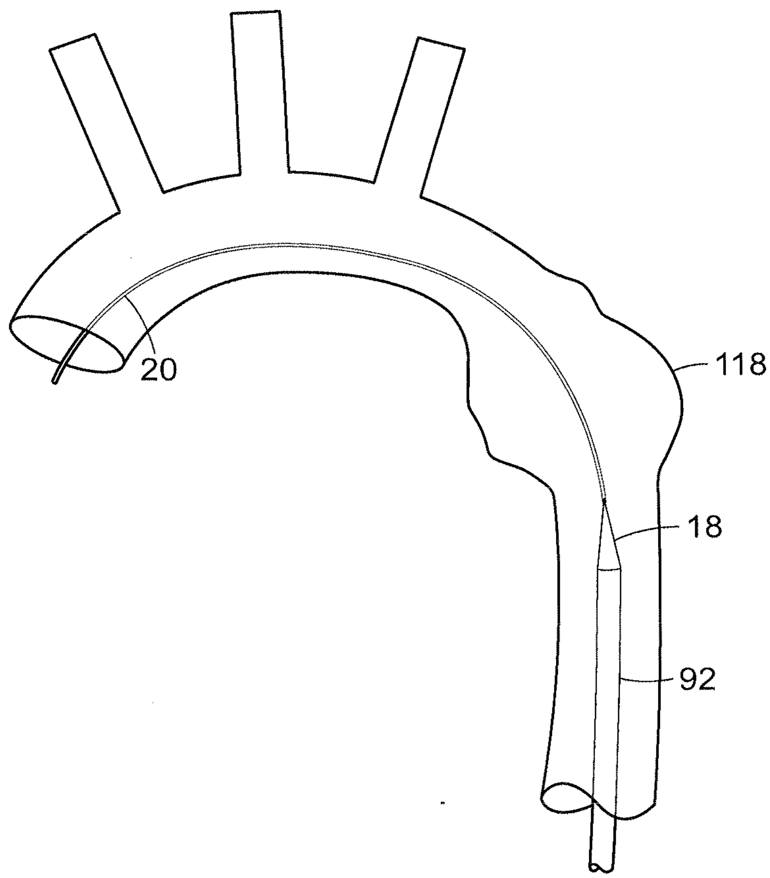

FIG. 14A

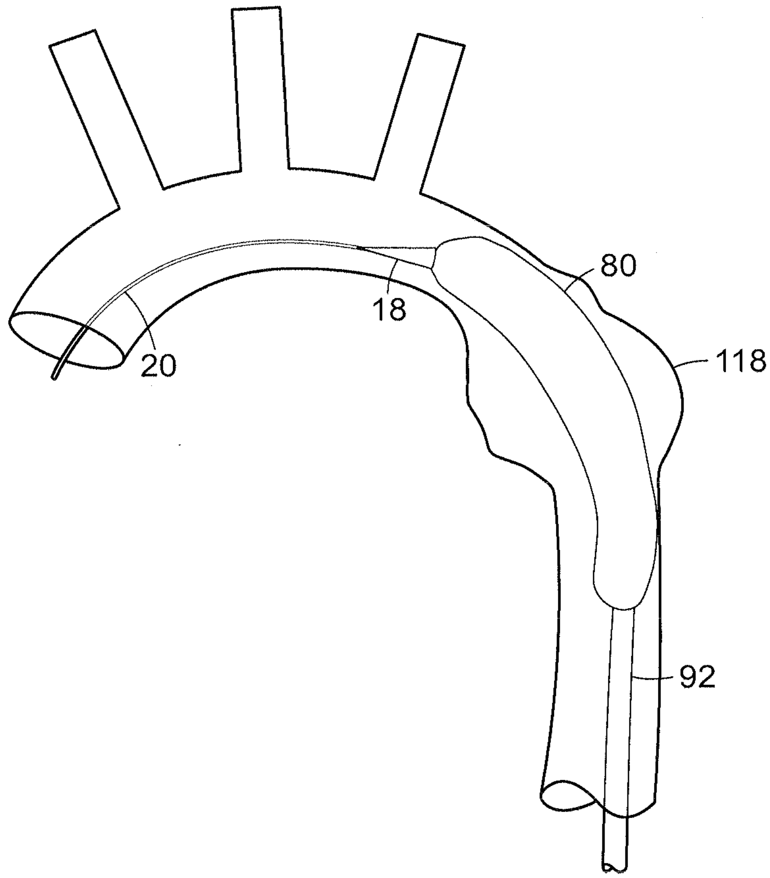

FIG. 14B

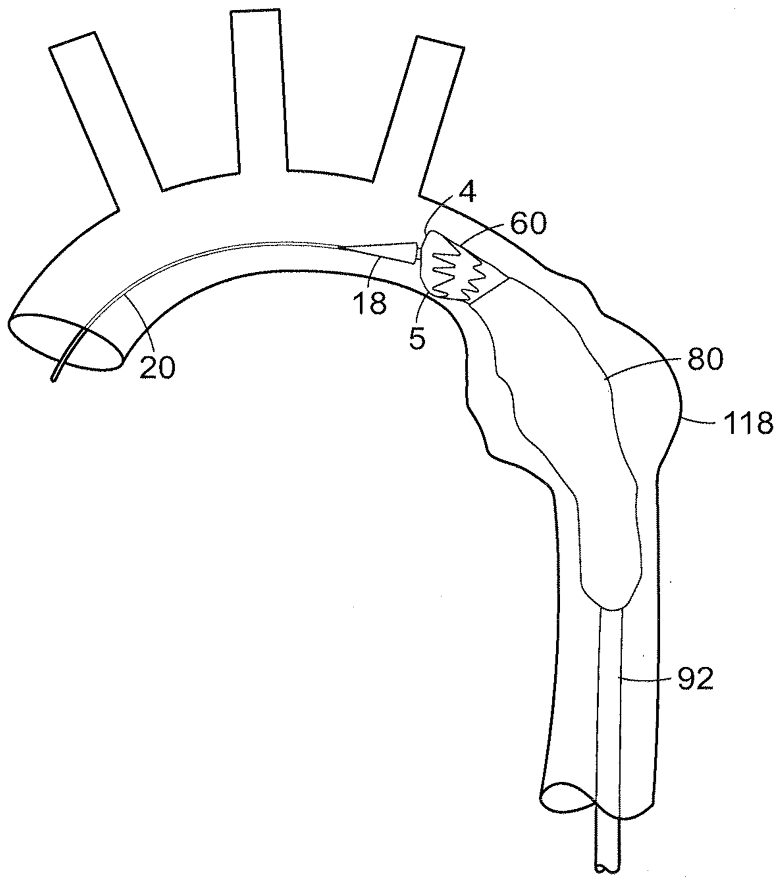

FIG. 14C

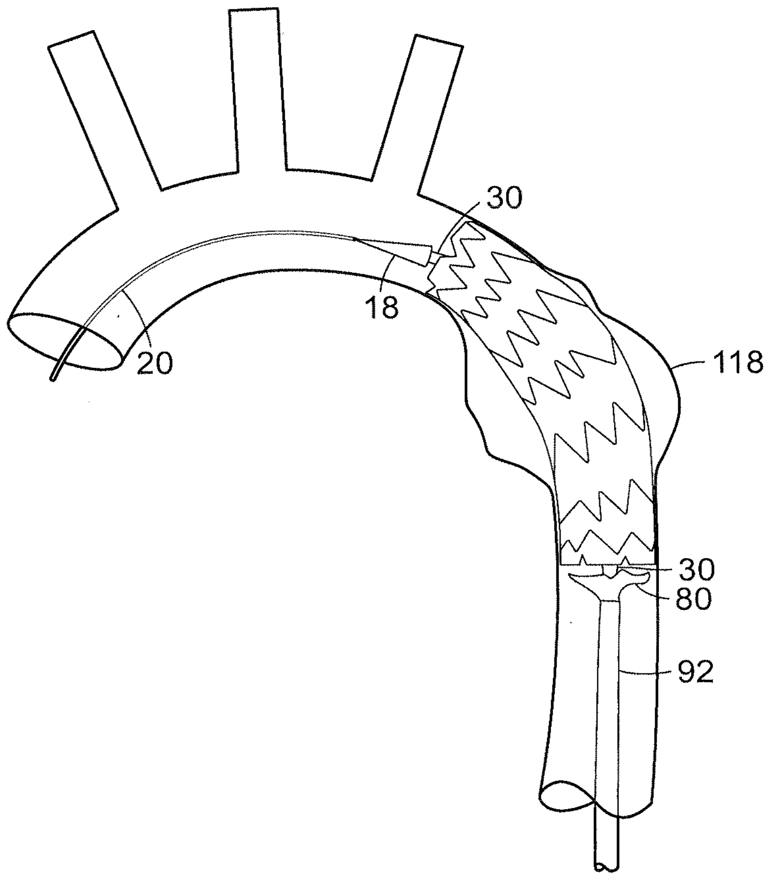

FIG. 14D

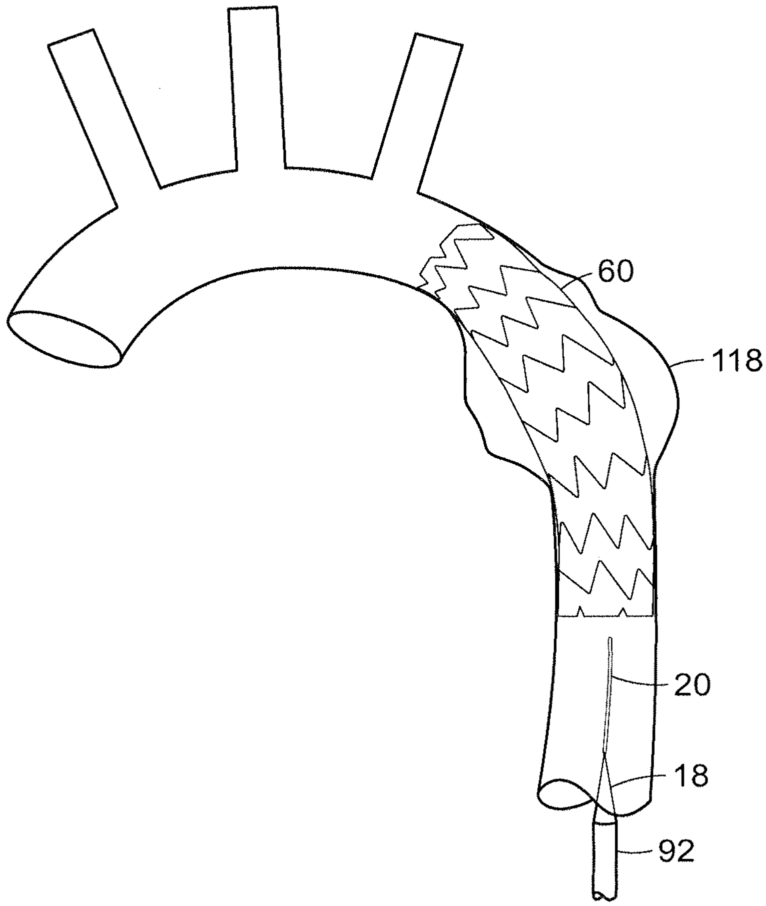

FIG. 14E

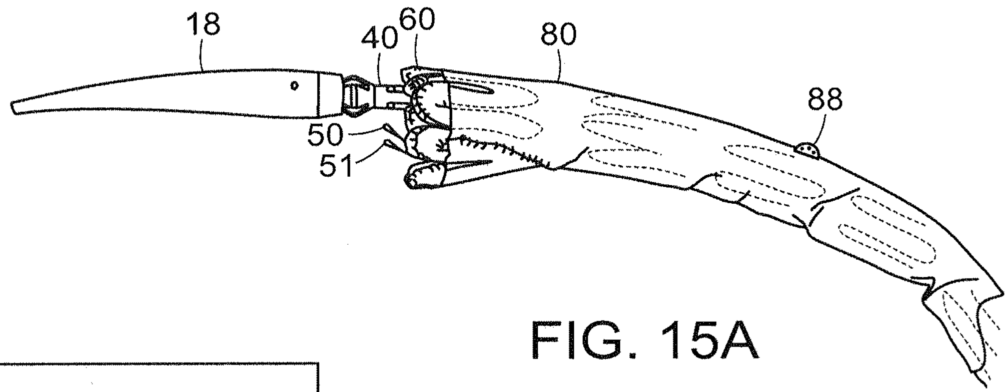

FIG. 15A

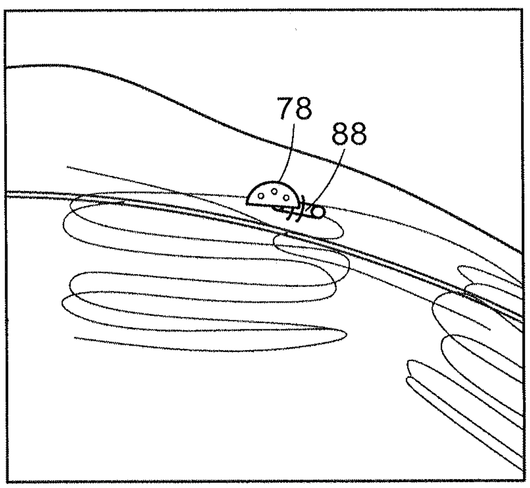

FIG. 15B

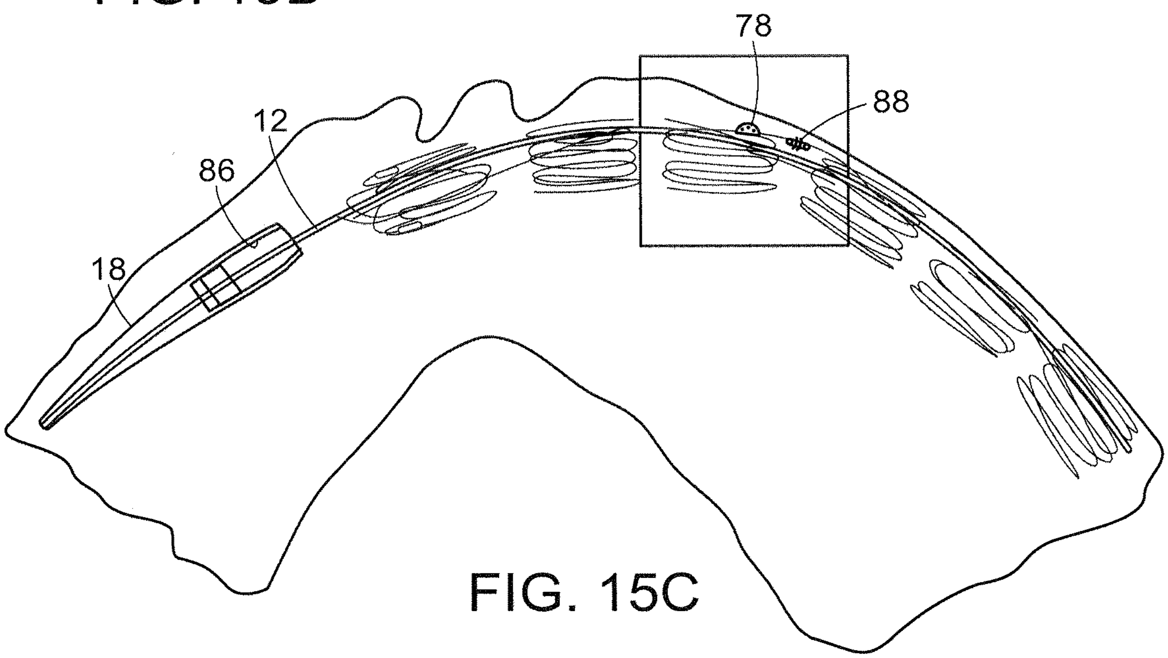

FIG. 15C

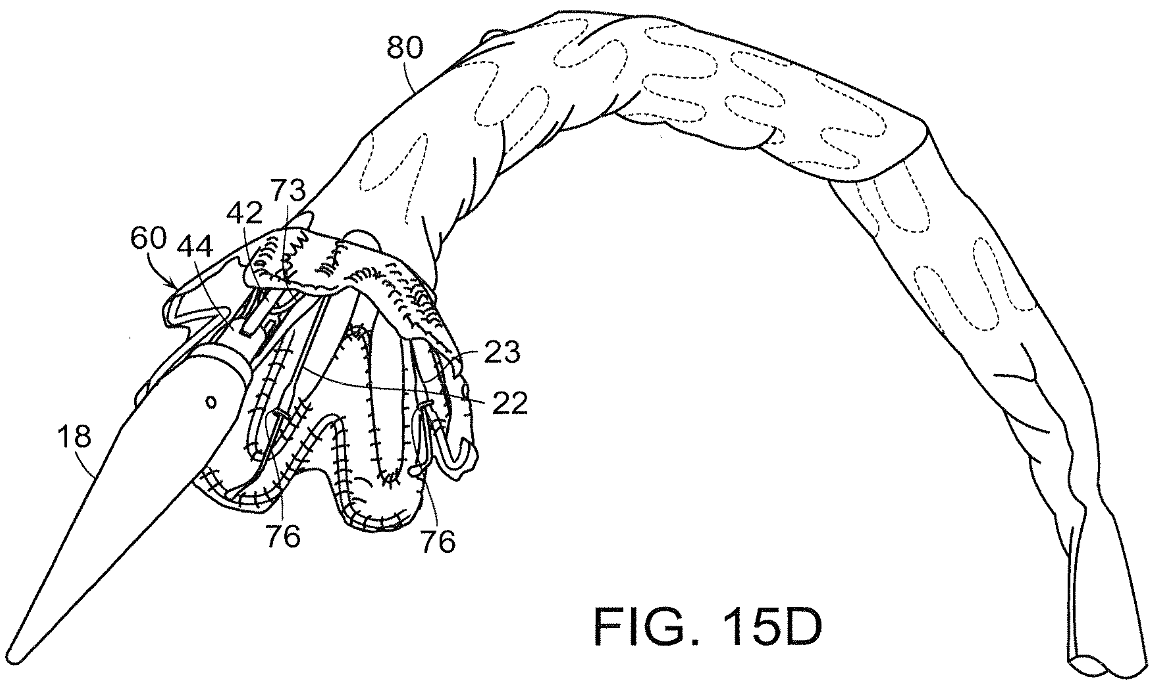

FIG. 15D

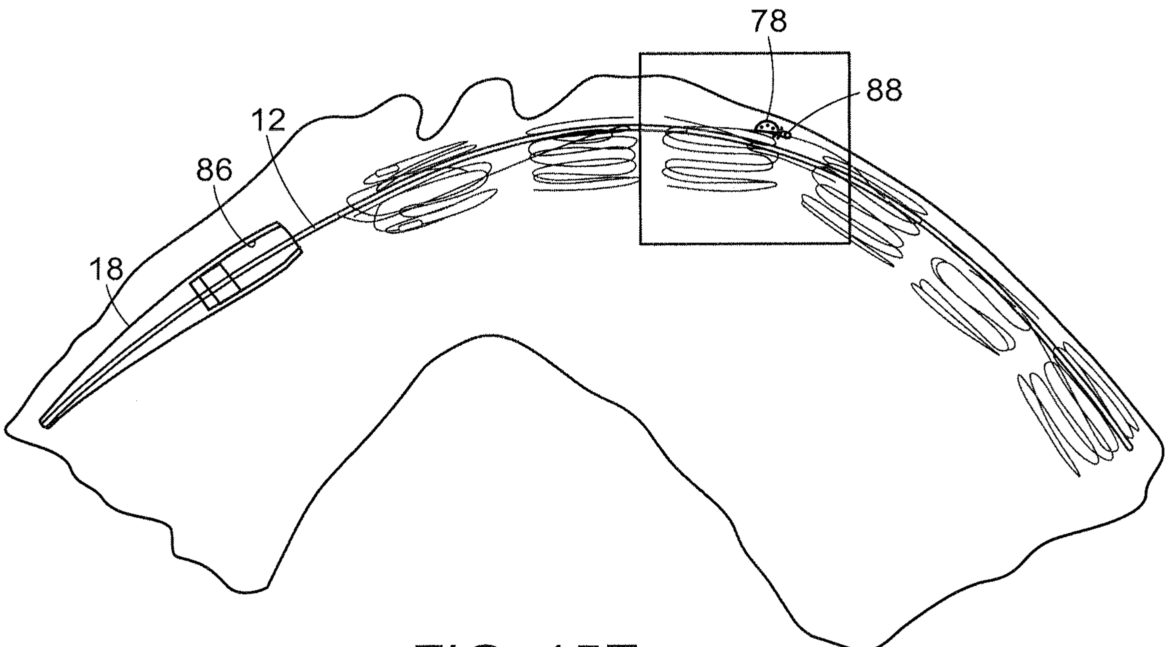

FIG. 15E

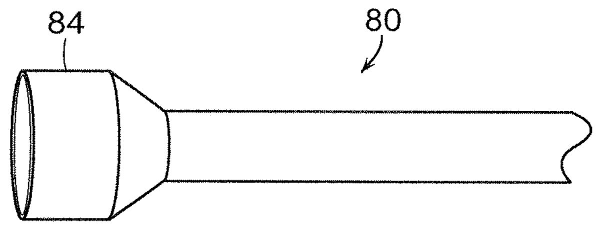

FIG. 16

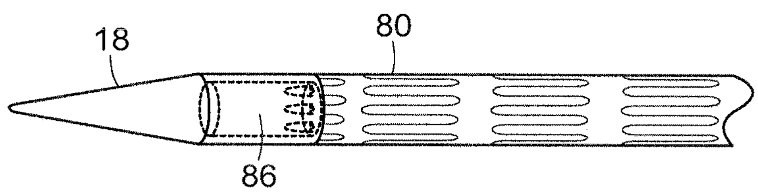

FIG. 17

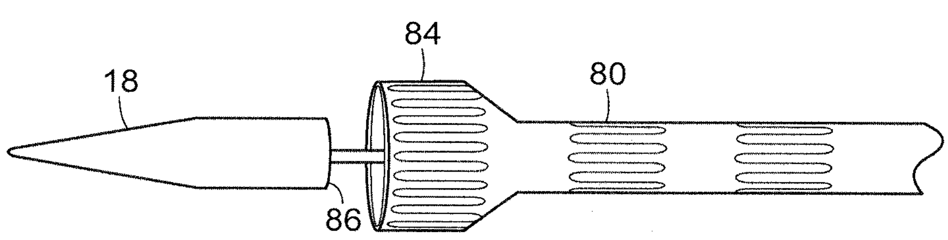

FIG. 18

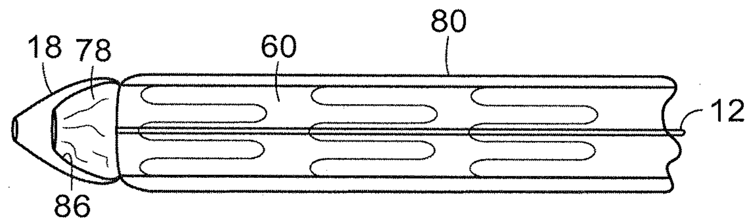

FIG. 19A

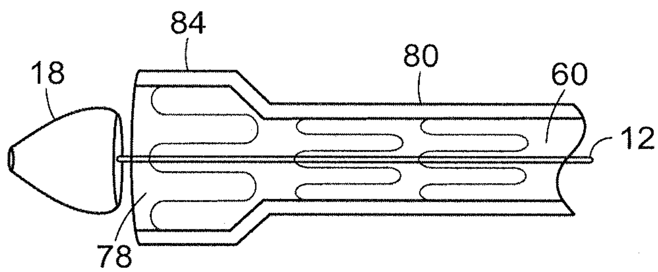

FIG. 19B

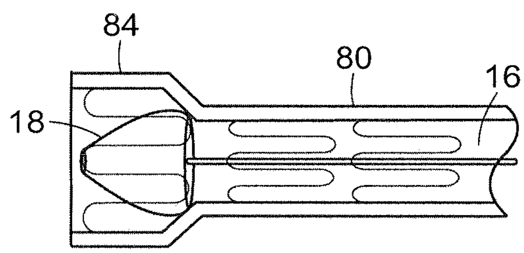

FIG. 19C

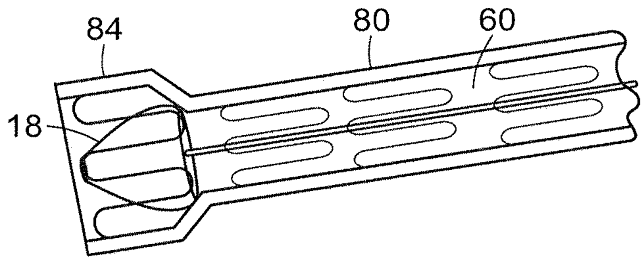

FIG. 19D

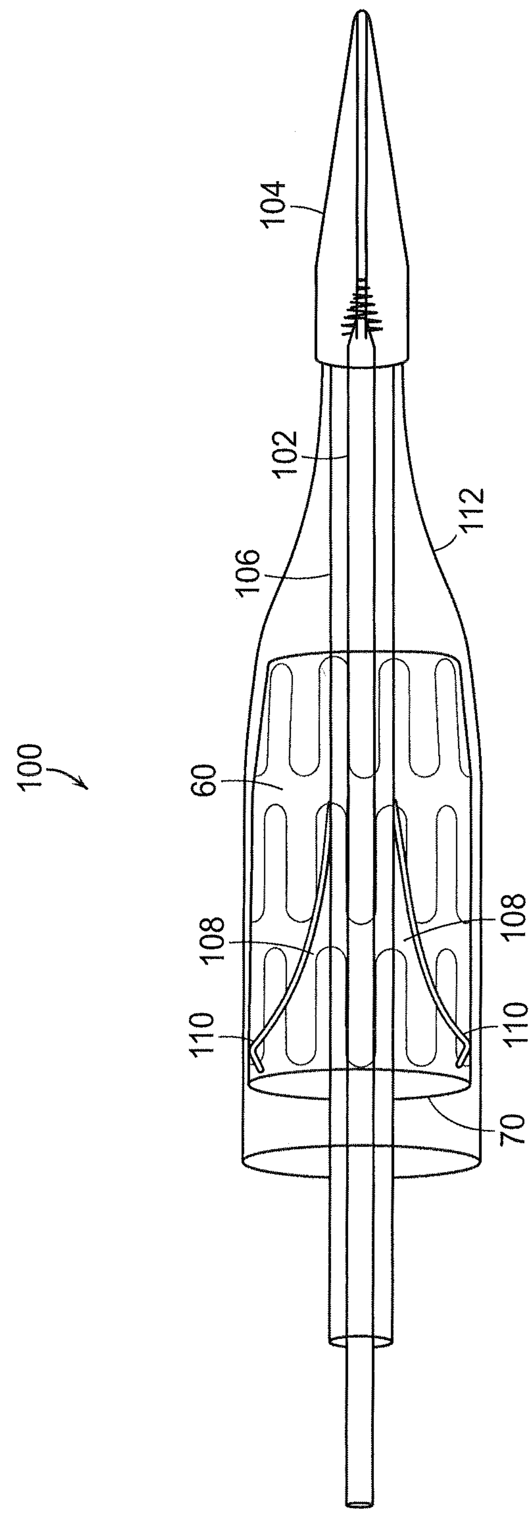

FIG. 20A

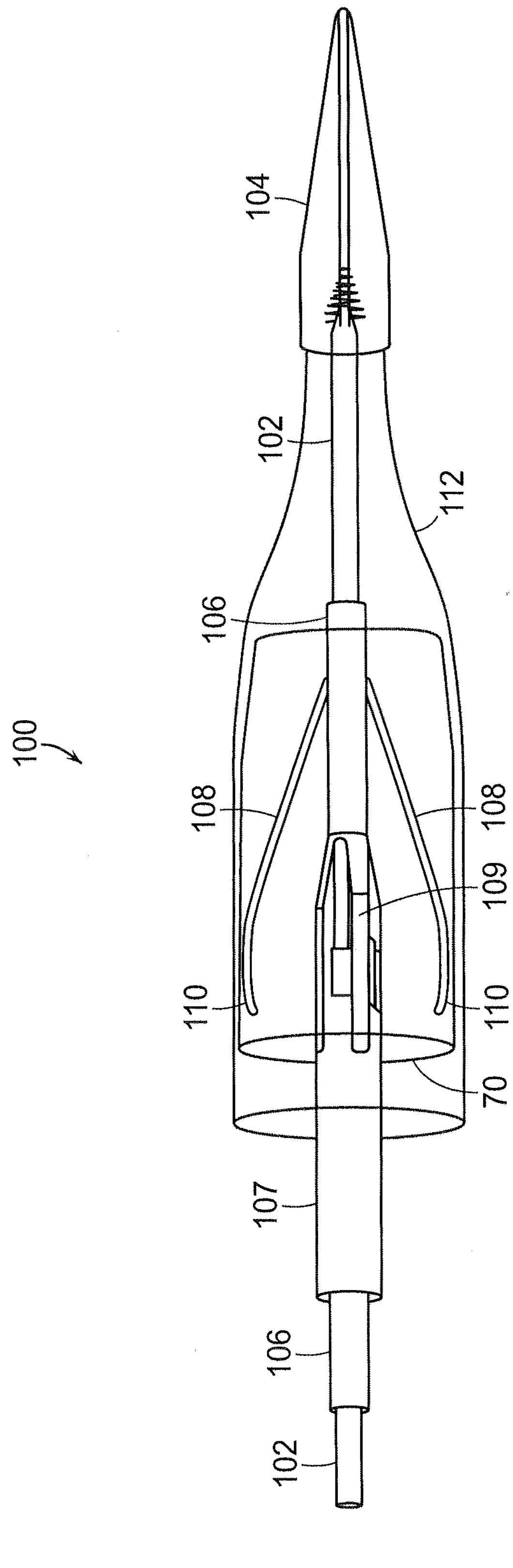

FIG. 20B

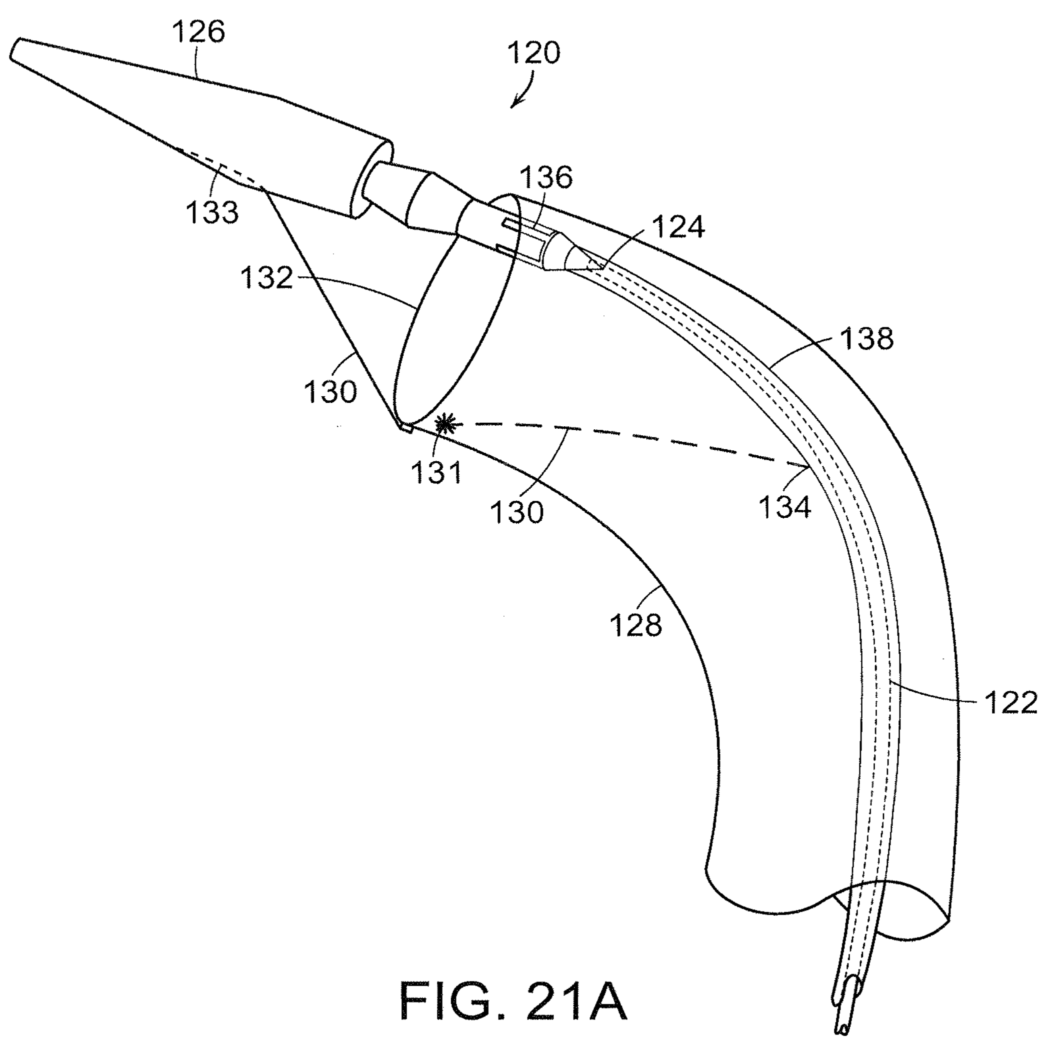

FIG. 21A

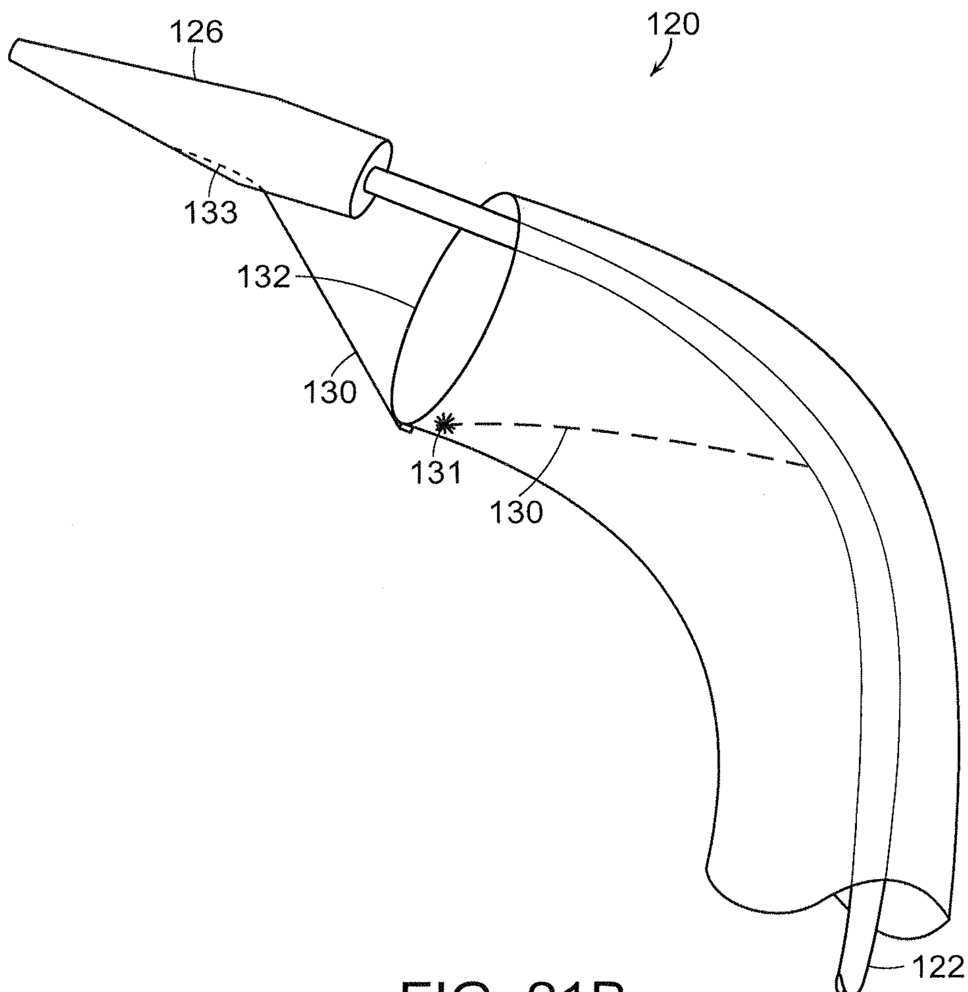

FIG. 21B

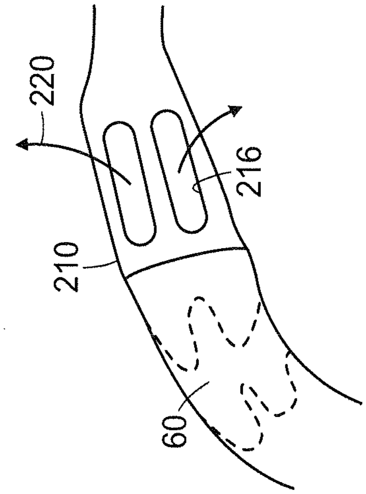

FIG. 22B

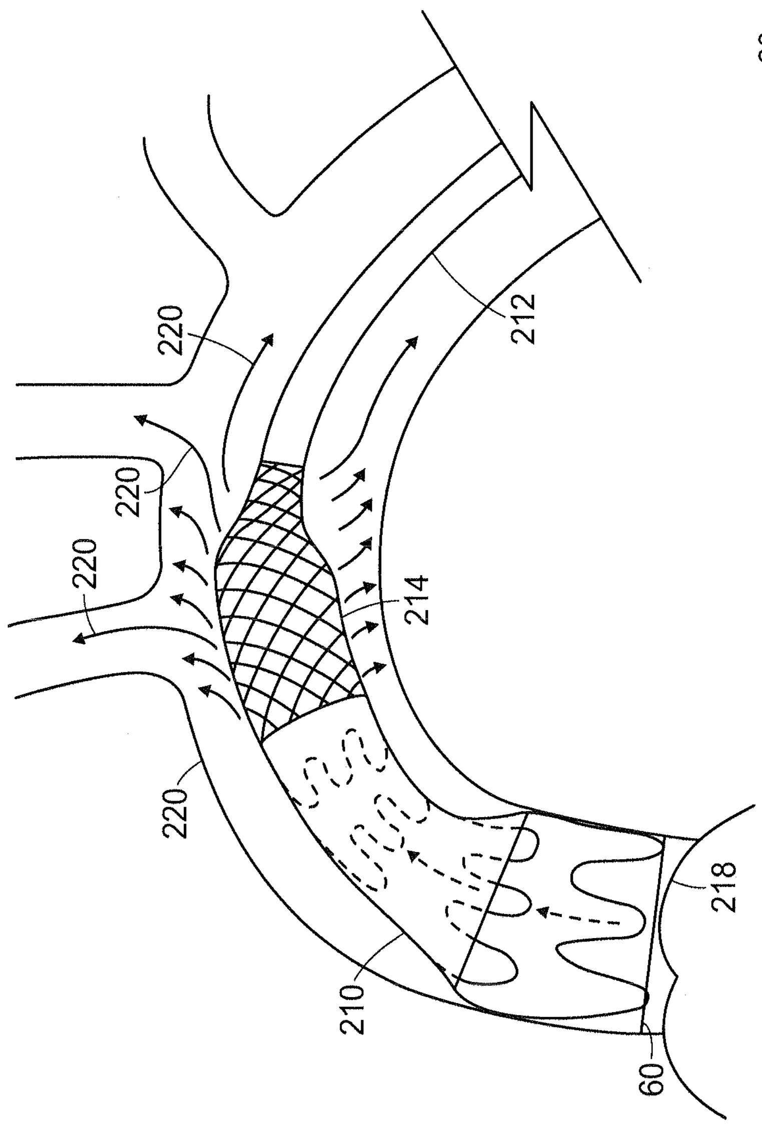

FIG. 22A